

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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EXPERT REPORT OF BRUCE ROSENZWEIG, M.D.

I. QUALIFICATIONS

I am currently an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. I received my MD degree in 1984 from the University of Michigan in Ann Arbor, Michigan. Following graduation from medical school, I completed an Obstetrics and Gynecology Residency at Michael Reese Hospital in Chicago. In 1988, I attended a one year pelvic surgery fellowship at State University of New York in Syracuse, New York. Following that fellowship, I attended a two year Urogynecology and Urodynamics fellowship at UCLA Harbor General Hospital in Torrance, California. After graduating from the Urogynecology fellowship, I became a faculty member at the University of Illinois in Chicago. I started a Urogynecology program at the University of Illinois and also was the residency program director. In 1998, I went into private practice, and subsequently established a private practice at Rush University Medical Center. I have also worked at John H. Stroger Hospital here in Chicago from May 2003 until November 2010 and Weiss Memorial Hospital as Associate Chair of Gynecology from February 2011 until July 2012. I have published numerous articles and given numerous

lectures on the topics of pelvic organ prolapse, urinary incontinence and repair of pelvic organ prolapse.

Throughout my career, I have performed over a thousand pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. I have also used numerous synthetic pelvic mesh products, including Ethicon's TVT, TVT Obturator, and Prolift. In addition, I have performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. I was also invited by Ethicon and attended both its Gynecare Prolift Training Seminar and TVT Obturator Seminar in Belgium. In addition, I was also invited and attended a Bard Avaulta training seminar.

A copy of my CV and Fee Schedule is attached as Exhibit "A" and a copy of my testimony for the last four years is attached as Exhibit "B". The documents I relied on for this report are contained in Exhibit "C" as well as those documents cited throughout this Report.

II. SUMMARY OF OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, sample products and depositions of Ethicon employees and witnesses. The corporate documents, sample products and depositions were supplied to me by counsel. A list of the materials reviewed and relied upon are attached hereto as Exhibit "C". All opinions I have are to a reasonable degree of medical and scientific certainty. I understand discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to corporate documents, depositions and the expert reports of both Plaintiff and Defense experts.

In general, my expert opinions can be summarized as follows¹:

- A. Ethicon's old construction mesh (Prolene), used in the TVT Exact, is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because it is too rigid or stiff, the pores are too small, it is heavyweight mesh, it degrades over time, and causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, biofilm formation and infections;
- B. Ethicon knew that the old construction mesh (Prolene) was not appropriate for use in its TVT Exact device but has failed to modify/change the laser cut mesh to a larger pore, lighter weight, less rigid mesh that would not increase the risk of erosions and sexual dysfunction, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction because of its economic interest in maintaining its competitive advantage in the MUS market and, therefore, Ethicon put profits before patient safety;
- C. Ethicon's warnings and disclosures of adverse events in its TVT Exact Instructions for Use ("IFU") are inadequate based on the adverse reactions and risks associated with the TVT Exact that were known to Ethicon from the time the TVT was first sold and marketed;
- D. Ethicon did not disclose information to physicians in its IFUs regarding characteristics of the old construction mesh (Prolene) that makes it unsuitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, including that it is too rigid, small pore, heavyweight mesh, it degrades over time, and causes chronic foreign body reactions, fibrotic bridging, and mesh contracture/shrinkage;
- E. Ethicon did not inform physicians and patients that Material Safety Data Sheets ("MSDS") for polypropylene resin used to manufacture polypropylene meshes warned against use of the mesh in a permanently implanted medical device due to incompatible with peroxides and that studies showed that it caused sarcomas in laboratory rats;
- F. Ethicon did not properly inform physicians that toxicity testing of the polypropylene mesh revealed that it was cytotoxic;

¹ This is not intended to be an exhaustive recitation of my opinions in this case. The full scope of my opinions are described in further detail in this report.

- G. Ethicon failed to test the TVT Exact;
- H. The first marketed TVT Exact's trocar and sheath were defective and Ethicon failed to inform physicians of those risks;
- I. Ethicon's promotional materials sent to physicians related to the TVT Exact were inaccurate and failed to reveal material information about complications/risks and conflict of interests regarding data promoted in the materials;
- J. Ethicon's collection and reporting of adverse events and complications to physicians and patients is misleading, inaccurate and incomplete; and
- K. The benefits of the TVT Exact are outweighed by the severe, debilitating and life changing complications associated with the TVT Exact.

III. BACKGROUND AND TREATMENT OPTIONS FOR SUI

A. Stress Urinary Incontinence ("SUI")

Approximately one of three women over the age of 45 years old has some form of urinary incontinence. The majority of those women do not seek medical advice or treatment for a variety of reasons.

In a continent individual, increased abdominal pressure is evenly distributed over the bladder, bladder neck, and urethra. The urethral sphincter is thus able to withstand this pressure and maintain continence. In a person with pure stress urinary incontinence (SUI), either the urethra is hypermobile or the sphincter is intrinsically deficient. In urethral hypermobility, the urethrovesical junction (UVJ) is displaced extra-abdominally, and the increased intra-abdominal pressure is unevenly distributed such that the sphincter can no longer withstand the pressure and urine leaks. With intrinsic sphincter deficiency (ISD), the UVJ is not hypermobile; however, the

maximal urethral closing pressure, the Valsalva leak-point pressure, or both are too low to withstand the increase in intra-abdominal pressure and, thus, urine leaks past the sphincter.

SUI is the involuntary leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise, in the absence of a bladder contraction. It has been estimated that 14% of women have SUI. SUI is a common type of urinary incontinence in women. Urodynamic proven SUI is found in approximately 50% of women presenting for evaluation of urinary incontinence. Symptomatic women with SUI have social or hygienic consequence from their urine loss. SUI can happen when pelvic tissues and muscles, which support the bladder and urethra, become weak and allow the bladder “neck” (where the bladder and urethra intersect) to descend during bursts of physical activity (urethral hypermobility). This descent can prevent the urethra from working properly to control the flow of urine. SUI can also occur when the sphincter muscle that controls the urethra weakens (intrinsic sphincter deficiency). The weakened sphincter muscle is not able to stop the flow of urine under normal circumstances, and when there is an increase in abdominal pressure. Weakness may occur from pregnancy, childbirth, aging, or prior pelvic surgery. It has been estimated that a majority of incontinent women have a combination of urethral hypermobility and ISD. Other risk factors for SUI include chronic coughing or straining, constipation, obesity and smoking. Finally occult or latent SUI is defined as a positive stress test, loss of urine with increased intra-abdominal pressure and between 350-450cc volume in the bladder, after the repositioning of pelvic organ prolapse (usually accomplished with a ring pessary carefully positioned as to avoid compression of the urethra) in an otherwise clinically continent patient.

B. Nonsurgical Treatment of SUI

There are numerous non-surgical treatments available to woman with SUI. First, Pelvic Floor Exercises: A type of exercise to strengthen the pelvic floor by contracting and relaxing the levator muscles that surround the opening of the urethra, vagina, and rectum. These exercises, commonly referred to as Kegel exercises, improve the pelvic floor muscles' strength and function. Kegel exercises can improve over-active bladders by increasing urethral resistance with can trigger the bladder to relax.

Second, Pessary: A removable device that is inserted into the vagina against the vaginal wall and urethra to support the bladder neck. This helps reposition the urethra to reduce SUI. These can be made of rubber, latex or silicon. Inserted into the vagina, a pessary rests against the back of the pubic bone and supports the bladder. Pessaries are available in various forms, including donut and cube shapes, and must be fitted by a healthcare provider. Some women who have stress incontinence use a pessary just during activities that are likely to cause urine leakage, such as jogging. Special incontinence pessaries have a 'knob', which fits under the urethra to elevate the midurethral to prevent urine loss.

Third, Transurethral Bulking Agents: Bulking agent injections are applied around the urethra that make the space around the urethra thicker, thus helping to control urine leakage. The effects are usually not permanent.

Fourth, Behavioral Modification: This includes avoiding activities that trigger episodes of leaking. Lifestyle modification can improve stress incontinence symptoms and include quitting smoking, weight loss, and allergy treatment during seasonal allergies.

Fifth, Urinary seals: These are adhesive foam pads, which women place over the urethral opening. The pad creates a seal and prevents the leakage of urine, providing incontinence

treatment. The pad is removed before urination and replaced with a new one afterward. The pad can be worn during exercise or physical activity, but not during sexual intercourse.

Sixth, Urethral insert: A thin, flexible tube that is solid rather than hollow (like a catheter) is placed into the urethra to block the leakage of urine. These small plugs are inserted into the urethra by women to prevent leakage, and are removed prior to urination. These inserts can be uncomfortable and may increase the risk of urinary tract infection.

Seventh, Bladder neck support device: This device is a flexible ring with two ridges. Once inserted into the vagina, the ridges press against the vaginal walls and support the urethra. By lifting the bladder neck, it provides better bladder control in women suffering from stress incontinence. The device needs to be sized to fit, and must be removed and cleaned after urination. Bladder neck support devices can be uncomfortable and may cause urinary tract infections.

C. Surgical Treatment of SUI

1. THE BURCH COLPOSUSPENSION

Retropubic approaches for the treatment of stress urinary incontinence include the Burch retropubic urethropexy (both open and laparoscopic) and the Marshall-Marchetti-Krantz (MMK) procedure. The goal of both of these procedures is to suspend and stabilize the urethra so that the urethrovesical junction (UVJ) and proximal urethra are replaced intra-abdominally and to recreate a firm backstop for intra-abdominal pressure. This anatomic placement allows normal pressure transmission during periods of increased intra-abdominal pressure restoring continence in a previously incontinent, hypermobile UVJ.

The Burch procedure was described in 1961. Initially, Burch described attaching the paravaginal fascia to the arcus tendineus. However, this was later changed to Cooper's ligaments

because these were felt to provide more secure fixation points, and less chance of infection as seen with the prior MMK procedure.

Patients with type III stress urinary incontinence (a fixed, nonfunctioning proximal urethra) are not ideal candidates for a Burch procedure as no hypermobility exists to correct. For the Burch procedure, a low Pfannestiel incision is made above the pubic bone in order to enter the space of Retzius (the anatomical space between the pubic bone and the bladder above the peritoneum in order to suspend the bladder and/or to perform a paravaginal repair. The procedure involves placing permanent stitches adjacent to the neck of the bladder and either proximal or distal to the bladder neck stitches on each side and suturing them Cooper's ligament which is attached to the pubic bone. The paravaginal repair is very similar except that the stitches are attached to the arcus tendentious linea pelvis. The likelihood of success of the Burch and the paravaginal repair procedures is reported to be 80-90% in most cases. Success means total elimination of the incontinence and patient satisfaction score greater than 90%. Improved means significant reduction of urine loss and greater than 70% improvement of patient satisfaction scores. Additionally, these retropubic procedures can be accomplished by the laparoscopic route. With respect to the selection of synthetic absorbable suture versus non-absorbable suture, and braided versus monofilament, no prospective randomized blinded data exist to suggest superiority of one suture material over another. However, recognized risks are associated with bone anchors. Modifications in the technique can be used if co-existent central defect cystocele is present and obliteration of the cul-de-sac can be performed to prevent enterocele or posterior vaginal wall prolapse after Burch colposuspension.

2. PUBOVAGINAL SLING PROCEDURES

Pubovaginal slings have excelled overall success and durable cure. The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (ie, proximal urethra) or mid-urethra, which acts as a physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

Historically, surgeons have used the fascia lata sling for recurrent SUI after a failed anti-incontinence operation. Furthermore, this operation is used extensively for the treatment of primary ISD. If the abdominal tissues are weak and attenuated or if the vaginal tissues are atrophied or in short supply, constructing a pubovaginal sling from the leg fascia lata can be performed. This procedure is more involved than the creation of the rectus fascial sling as it requires a second incision to harvest the fascia lata and healing in an area remote for the index procedure.

An alternative to a long rectus sling is construction of a short sling from a much smaller piece of abdominal fascia (rectus fascia suburethral sling). The surgical procedure is similar to that used for the rectus fascia pubovaginal sling, except that the harvested fascial tissue is much smaller and the operation time shorter. The advantage of this procedure is its simplicity. No extensive dissection in the suprapubic area is necessary, and the postoperative result is similar to that of the full-length fascial strip sling.

An alternative to a long fascia lata sling is the use of a postage stamp-sized patch of fascia lata from the outer thigh (fascia lata suburethral sling). The surgical procedure is similar to that for the fascia lata pubovaginal sling, except the harvested fascia is much smaller. This operation does not require extensive dissection in the thigh area, and the postoperative result is similar to that of

the full-length fascia lata strip sling. Postoperative convalescence is shorter than that of the fascia lata pubovaginal sling procedure.

The vaginal wall suburethral sling helps restore urethral resistance by increasing urethral compression and improving mucosal coaptation of the bladder neck. This operation is attractive because it is simple and easy to perform. Postoperative complications are minimal, and the recuperative period is short. Vaginal sling surgery is relatively contraindicated in elderly women with atrophic vaginitis. If recognized before surgery, the atrophied vaginal wall may be revitalized with the administration of vaginal estrogen cream or tablets for 3-6 months.

A clear contraindication to pubovaginal sling surgery is pure urge incontinence or mixed urinary incontinence (MUI) in which urge is the predominant component. An inherent risk of any sling procedure is de novo or worsening urge symptoms; thus, surgeons must identify and treat the presence of an urge component before surgery.

Conversely, poor detrusor function is a relative contraindication to pubovaginal sling surgery because the potential for urinary retention is increased. Women with absent or poor detrusor function in the presence of SUI are at a higher risk of experiencing prolonged postoperative urinary retention.

3. MIDURETHRAL SYNTHETIC SLINGS

Based on the “Integral theory of female incontinence,” Prof. Ulmsten developed a midurethral procedure to treat stress urinary incontinence. The first reports of this procedure appeared in 1996 as an intravaginal slingoplasty. The “tape” was placed through a small vaginal incision at the midurethra, brought through the urogenital diaphragm through the retropubic space and exited through small suprapubic incisions. The operation was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and also by creating a

midurethral hammock for support of the urethra during stress events. The procedure was described to have a success rate of 85-90% with an additional 5-10% significantly improved. The Gynecare TVT system was introduced in the US in November of 1998. Early studies showed that the risk of bladder perforation during the procedure occurred 5-10% of cases and vascular injury without hematoma formation occurred in 2-5% of patients.

In an attempt to decrease the risk of bladder perforation and vascular injury, a “top-down” approach to trocar placement was promoted as the SPARC procedure, introduced in the US in 2001 by American Medical Systems (AMS). The next modification of the midurethral sling came in 2001 when Delorme described his results for the use of the obturator membrane and inner thigh for passage of the sling material. The proposed advantage was avoidance of the retropubic space, thus avoiding bladder perforation and retropubic vascular injury. The trocars were passed from the inner thigh through the obturator membrane from an “outside – in direction”.

The next modification came from de Leval in 2003, with the “inside-out” trocar placement for the transobturator sling. This modification came around 2006 with the release of the mini-slings, or single incision slings, which use support devices at the ends of shorter mesh lengths to accomplish fixation without the need for a secondary cutaneous exit point. The mini-slings could be placed in a retropubic or “U” fashion or a hammock or “H” fashion.

The FDA concluded in 2011 that there was higher peri-operative blood loss, higher mesh exposure and greater need for surgical re-intervention in the TVT-Secur (mini-sling) patients.

IV. EXPERT OPINIONS

A. ETHICON'S PROLENE MESH IS NOT SUITABLE FOR ITS INTENDED APPLICATION.

Polypropylene mesh (Prolene), like that contained in the TVT Exact, has many characteristics that makes it unsuitable for use as a product intended for permanent implantation in the human vaginal floor. These characteristics include the following: (1) excessive rigidity of laser-cut mesh; (2) degradation of the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh.

As a result of these and other inadequacies with the mesh, and for the reasons set forth below, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT Exact causes a multitude of injuries, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury of the obturator, pudendal and other pelvic nerves, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, Ethicon's TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

1. LASER-CUT MESH

The Prolene mesh in the TVT Exact is laser cut in the manufacturing process, as opposed to being mechanically cut.² This means that the plastic mesh is cut into strips using a laser instead

² ETH.MESH.00576844; ETH.MESH.03546997; Smith Dep. (5/15/14) 48:11-17.

of a cutting blade.³ The result is that the mesh itself is stiffer than mechanically cut mesh.⁴ In fact, an internal memo from Becky Leibowitz to Paul Parisi and Dan Smith in late 2004 found that when the laser cut mesh was stretched it became about three times stiffer than the machine-cut TVT mesh.⁵ Just four years later, before the launch of the TVT Exact, it is noted that no clinical study had been done regarding the differences between laser cut mesh and mechanical cut mesh.⁶ Within a year of the TVT Exact launch, Ethicon began receiving complaints on the TVT Exact regarding its use of the stiffer laser cut mesh.⁷ Importantly, while these discussions about the differences between laser cut mesh and mechanical cut mesh were going on, most surgeons using the TVT products did not know what type of mesh they were using.⁸ Thus, there was no way for doctors to adjust tensioning differently or be aware that the mesh is stiffer, or to warn patients of an increased risk of erosions. Even as late as February 2015, Ethicon still had not done a single study to determine whether the laser cut mesh causes more erosions than mechanical cut mesh, whether laser cut mesh increases the amount of pain a patient will experience, or any critical outcomes.⁹

The difference in the stretch profile between mechanically cut and laser cut mesh also led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,¹⁰ and Jean de Leval, the inventor of TVT-O, to refuse to use, and question the use, of laser cut mesh.¹¹ Moreover,

³ Lamont Dep. (9/11/13) 12:13-13:14.

⁴ ETH.MESH.01809080-01809081.

⁵ ETH.MESH.01809080.

⁶ ETH.MESH.02090196.

⁷ ETH.MESH.00576844.

⁸ ETH.MESH.009911296.

⁹ Trial Testimony of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3433:27-3434:18.

¹⁰ Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int J Urogynecol J Pelvic Floor Dysfunct* 1998;9:210–3.

¹¹ ETH.MESH.16416002-16416004; ETH.MESH.04048515-04048520.

according to the J&J Defendants, use of the laser cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.¹² Additionally, laser cut mesh was never assessed on its own in a clinical trial.¹³ Ethicon's Medical Director, Piet Hinoul, even noted in 2011, after the launch of the TVT Exact, that there was is no literature that allows him to discriminate which clinical trials have used laser cut versus mechanical cut.^{14 15}

2. THE PROLENE MESH IN TVT EXACT DEGRADES OVER TIME

The mesh used in the TVT Exact was originally designed in 1974 for use in the abdomen for treatment of hernias and it has not changed since then.¹⁶ Ethicon describes this mesh as the "old, old" mesh: "The first generation (old, old) mesh is utilized currently in the TVT product...."¹⁷ Dan Smith testified that even when the original hernia mesh was updated for use in the abdomen, Ethicon continued to use the "old, old" mesh for TVT Exact and does to this day, as follows:

Q: So TVT kept the old when hernia changed to the new.

A: Also known as original, yes.

Q: The mesh that was used in the TVT-R is called sometimes by Ethicon in documents old construction or original mesh; correct?

A: Yes. Yes.¹⁸

In the late 90's Ethicon determined that, in the hernia applications, it was safer to move to a lighter weight, larger pore mesh. Ethicon made a similar determination for meshes to be used in

¹² ETH.MESH.06040171-06040173.

¹³ ETH.MESH.03941617.

¹⁴ ETH.MESH.00576844.

¹⁵ Notably, Dr. Hinoul's trial testimony in *Batiste v. Ethicon*, is in direct contradiction to his statement in this email that all of the TVT-Os tested in his study were laser cut. Presumably in order to convince the doctor to use the TVT Exact.

¹⁶ Smith Dep. (2/3/2014) 723:9-724:6.

¹⁷ Smith Dep. (2/3/2014) 723:9-724:6.

¹⁸ Smith Dep. (2/3/2014) 723:9-724:6.

the pelvic floor.¹⁹ However, Ethicon never updated the “old, old” hernia mesh used in the TVT Exact.²⁰ Notably, in my opinion this makes science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT Exact mesh as Ethicon chose to move to large pore, light weight meshes in these areas, but not for TVT Exact.

The placement of permanent polypropylene mesh in the human vagina creates problems because of the chemical composition and structure of the mesh and the physiological conditions of the vagina and the surrounding tissues. There have been numerous studies over the last 30 years which have shown polypropylene to be chemically reactive and not inert, with flaking and fissuring demonstrated by scanning electron microscopy, which leads to degradation and release of toxic compounds into pelvic tissues. This process enhances the inflammatory and fibrotic reactions within the tissues in the pelvic floor, causing a multitude of problems.²¹ There have been studies suggesting that oxidation of the mesh occurs because of the polypropylene and the conditions in which it is placed.²² The oxidation causes the mesh to degrade, crack and break apart.²³ In a recent study, 100 pelvic mesh implants were compared and over 20% showed degradation to mesh fibers.²⁴

¹⁹ See, e.g., ETH.MESH.07455220 (discussing mesh shrinkage/contracture and stating: “Since this phenomenon occurs most frequently in small pore, heavy weight mesh, ETHICON has developed large pore, light weight meshes, i.e. GYNECARE GYNEMESH PS Nonabsorbable Prolene Soft Mesh....”).

²⁰ Smith Dep. (2/3/14) 829:16-829:19.

²¹ Coda A., *Hernia* 2003;7:29; Jongbloed, WL, “*Degradation of Polypropylene in the Human Eye: A SEM Study*,” *Doc. Ophthalmol.*, 1986 64(1:143-152); Skrypunch, O.W., “*Giant Papillary Conjunctivitis from an Exposed Prolene Suture*,” *Can. J Ophthalmology*, 1986 21(5: 189-192).

²² Costello C., et al., “*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient*,” *Surgical Innovation*, 2007, 143:168- 176).

²³ *Id.*

²⁴ Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H, “*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*,” *J Biomed Mater Res B Appl Biomater*, 2007, Oct 83(1:44-9).

Because of the structural complexities of the vagina and the nature of the chemicals ordinarily found in the vagina and its surrounding tissues, there are several reasons why polypropylene presents unique problems when placed in the vagina. An Engineering Bulletin from Propex, entitled “*EB-405, The Durability of Polypropylene Geotextiles for Waste Containment Application*,” from 2011, states that, “[P]olypropylene is vulnerable to the following substances: highly oxidized substances such as (peroxide), certain chlorinated hydrocarbons (halogenated hydrocarbons), and certain aromatic hydrocarbons.”²⁵ It is well known to physicians with expertise in the pelvic floor that vaginal and perivaginal tissues are ready sources for peroxide. The vaginal species lactobacillus produces hydrogen peroxide and lactic acid from glycogen that is produced in the squamous cells of the vagina. Estrogen is the catalyst for the production of glycogen from the vaginal cells. It is also well known that hydrogen peroxide produced by the lactobacillus species is important in controlling the vaginal micro-flora.

In fact, the vagina is a ready source of hydrogen peroxide production. In a manuscript from M. Strus, “*The In Vitro Effects of Hydrogen Peroxide on Vaginal Microbial Communities*,” the authors show the amount of hydrogen peroxide produced by the lactobacillus species.²⁶ “Hydrogen Peroxide reached concentrations of 0.05 to 1.0 mm, which under intensive aeration increases even up to 1.8 mm.”²⁷ These results confirmed the previous results of M. Strus in the publication, “*Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Micro-flora*,” Med Dosw Mikrobiol, 2004: 56(1:67-77).

²⁵ Citing Schneider H., *Long Term Performance of Polypropylene Geosynthetics, "Durability and Aging of Geosynthetics*, Koerner, RM, Ed., (Elsevier 1989) 95-109.

²⁶ Strus, M., et al., *The In Vitro Effect of Hydrgen Peroxide in Vaginal Microbial Communities*, FEMS Immunol Med Microbiol, 2006 Oct; 48(1:56-63).

²⁷ *Id.*

It is also known that aromatic hydrocarbons can be found in the human body. In a paper from HB Moon entitled, "*Occurrence and Accumulation Patterns of Polycyclic Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females*," *Chemosphere* 2012 (86:485-490), these aromatic hydrocarbons were noted to be present in, "[t]otal concentrations of PAHs and SMCs in adipose tissues rang[ing] from 15 to 361 (mean:119) ngg(-1) lipid weight and from 38 to 253 (mean:106) nng(-1) lipid weight respectively.... The results of this study provide baseline information on exposure of PAHs and SMCs to the general population in Koreans."

It has also been determined that halogenated hydrocarbons can be found not only in adipose tissue but also the blood stream. A paper entitled, "*Determination of Volatile Purgeable Halogenated Hydrocarbon in Human Adipose Tissue and Blood Stream*," from the *Bulletin of Environmental Contamination and Toxicology*, Volume 23, Issue 1, pp 244 – 249 published in 1979, found halogenated hydrocarbons, pesticide by-products, both in human adipose tissues and the blood stream. In a subsequent paper from 1985 in *Environmental Health Perspectives*, Volume 60, pp. 127-131, Henry Anderson, in his paper entitled, "*Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure*," also found these pesticide by-products in human adipose tissue. Accordingly, the body location where the polypropylene mesh is being placed can expose it to known chemical degradation agents.

However, chemical degradation is not the only way that polypropylene degrades *in vivo*. In a paper from N Das in the *Journal of Biotechnology Research International*, Volume 2011, Article ID 941810, entitled, "*Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview*," found that various bacteria such as *Pseudomonas* species, *Bacillus* species, *Mycobacterium* and *Corynebacterium* species, which are present in a woman's vagina,

can degrade petroleum hydrocarbons. Also fungi such as the *Candida* species, also present, can degrade petroleum-based hydrocarbons.²⁸ Microbial agents that can be found inside the normal and abnormal flora of the human vagina such as *Candida* and, with certain pelvic infections such as *Bacillus* and *Pseudomonas*, can be a source of biological degradation of polypropylene products.

A paper entitled, “*Health, Safety and Environment Fact Sheet: Hazardous Substances - Plastics*,” from CAW/TCA (www.caw.ca), August 2011:343, found that polypropylene degradation products and residues can form carbon monoxide, acrolein, aldehydes and acids, qualifying these health hazards as toxic and irritants. In a paper from D Lithner in 2011 at 4, entitled, “*Environmental and Health Hazards of Chemicals in Plastic Polymers and Products*,” University of Gothenburg, it is stated that, “[n]on-biodegradable polymers can be degraded by heat, oxidation, light, ionic radiation, hydrolysis and mechanical shear, and by pollutants such as carbon monoxide, sulphur dioxide, nitrogen oxide and ozone. This causes the polymer to get brittle, to fragment into small pieces and to release degradation products.” (Citations omitted.) Lithner continues, “[o]ther substances (besides monomers) are often needed for polymerization to occur, for instance initiators, catalysts, and, depending on manufacturing process, solvents may also be used. The resulting plastic polymer can be blended with different additives, for instance plasticizers, flame retardants, heat stabilizers, antioxidants, light stabilizers, lubricants, acid scavengers, antimicrobial agents, anti-static agents, pigments, blowing agents and fillers, and is finally processed into a plastic product. There are many different plastic polymers and several thousand different additives, which result in an extremely large variation in chemical composition of plastic products.” *Id.* at 6 (citations omitted). “Since plastic products are composed of many

²⁸ Das, N , et al., *Review Article: Microbial Degradation of Petroleum Hydrocarbon Contaminants: an Overview*, J Biotech Res Intl, 2011, Article ID 941810, 1-13.

different chemicals, and the main part of these [are] broken down into something completely different; this complicates the prediction.” *Id.* at 8. “The type and quantity of degradation products formed may also be influenced by degradation mechanisms, presence of polymerization impurities, and surrounding factors, e.g. temperature and oxygen.” *Id.* at 9. “Few studies combining leaching tests with toxicity tests have been performed on plastic products.” *Id.* at 12. The available peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body dates back to the 1960’s and has been reported in numerous such publications.²⁹

Two of the more important and salient articles regarding reported degradation in explanted surgical meshes (hernia and pelvic floor) are the Costello and Clave articles. In his paper, “*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Implants from a Single Patient*,” Prof. C Costello reported that hernia mesh made of polypropylene oxidized and degraded as a result of the metabolites produced by phagocytic cells during the body’s inflammatory reaction to the mesh. High-magnification photographs showed cracking and peeling of the polypropylene fibers. Ethicon referenced this article in internal emails.³⁰

Another article by A Clave, “*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*,” also displayed high magnification photos of polypropylene fibers from explanted meshes and, in this case, the meshes were explanted from women’s pelvic floor tissue.³¹ The heavyweight meshes showed even greater cracking than the lower density meshes, but according to Prof/Dr. Clave, ALL 84 of the polypropylene explants

²⁹ Liebert, T, et al., *Subcutaneous Implants of Polypropylene Filaments*, J Biomed Mater Res. 1976 (10:939-951); Williams, D., *Review of Biodegradation of Surgical Polymers*, J Materials Sci, 1982 (17:1233-1246); Oswald, H.J., et al., *The Deterioration of Polypropylene By Oxidative Degradation*, Polymer Eng Sci, 1965 (5:152-158).

³⁰ ETH.MESH.005588123.

³¹ Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.

examined showed degradation. Oxidation of the implanted mesh due to free radical attack through the synthesis of peroxides, superoxides and hypochlorous acid during the chronic inflammatory phase was listed as just one potential cause for the oxidative degradation within the “septic environment” in which the pelvic meshes are placed.

Given the information available to Ethicon in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman’s body, what the clinical implications for the woman would be and whether some women’s body’s would react differently to the mesh and degradative process and its by-products.

Ethicon’s Daniel Burkley, a Principal Scientist at Ethicon, testified that the science supported the conclusion that mesh could shrink, contract and degrade. Specifically, Mr. Burkley agreed that the risk of degradation increases when you have a severe inflammatory response with mesh implanted in a contaminated field.³² Mr. Burkley also testified that polypropylene mesh in human beings is subject to some slight degree of surface degradation.³³ He agreed that degradation might be better understood if Ethicon studied or tested a product that is permanently implanted in women.³⁴ In fact, according to Mr. Burkley, Ethicon only conducted one study related to degradation and Prolene material. This study consisted of a Prolene suture implanted

³² Burkley Dep. (5/22/13) 184:17-24.

³³ Burkley Dep. (5/22/13) 206:2-11

³⁴ Burkley Dep. (5/22/13) 206:12-25.

into dogs.³⁵ Mr. Burkley testified that the study and photos from the dog actually showed that the Prolene material used in TVT Exact degraded and was still degrading after 7 years.³⁶

It is now clear from Ethicon's internal documents that Mr. Burkley was incorrect when he said that Ethicon only performed one study related to degradation of Prolene. Contrary to Mr. Burkley's claim, he and other Ethicon scientists were involved in a Prolene human explant study that was conducted in 1987 which found that Prolene degrades while in the body. According to Ethicon's documents, Ethicon's scientists received 58 Prolene human explants from Professor Robert Guidon³⁷ which were analyzed by Ethicon's scientists using scanning electron microscopy ("SEM"). The SEM study revealed that 34 of the 58 Prolene explants (58%) were cracked. Further studies, including FTIR and melt point analysis, were conducted by Ethicon's scientists to determine the cause of the cracking observed in Prof. Guidon's explants. In a report authored by Mr. Burkley on September 30, 1987, he concluded that the Prolene explants had insufficient antioxidants to protect them from oxidation which led to *in vivo* degradation of the Prolene devices.³⁸ Importantly, Ethicon has not made any changes to Prolene since it was introduced to the market, except that, in 2011, they reduced the amount of Sanatanox (another antioxidant), which could potentially make Prolene more, not less, susceptible to oxidized degradation.³⁹ Thus, Ethicon's internal studies clearly demonstrate that Ethicon's scientists had concluded that Prolene can degrade while implanted in the human body.

³⁵ ETH.MESH.05453719 (Seven year data for ten year Prolene study: ERF 85-219).

³⁶ Burkley Dep. (5/23/13) 315:8-13.

³⁷ DEPO.ETH.MESH.00004755.

³⁸ ETH.MESH.12831391 at ETH.MESH.12831392.

³⁹ ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentations

Ethicon subsequently hired an outside consulting firm to resolve the cause of the erosion of its surgical meshes for the pelvic floor. In a June 22, 2011 report, PA Consulting Group informed Ethicon that, “[p]olypropylene can suffer from degradation following implant... a process which initiates after a few days post implantation in animal studies.”⁴⁰ The consulting report discusses numerous images of polypropylene mesh that show “physical degradation” of the mesh.⁴¹ In addition, in a 2009 presentation, Ethicon Medical Director Piet Hinoul stated that meshes are not biologically inert.⁴²

I have personally seen mesh that is broken, cracked and looks different from when it came out of the package. Interestingly, despite years of scientific literature, its own internal dog study and reports from consultants it hired that degradation of mesh occurs, Ethicon’s Instructions for Use (IFU) continues to claim to this day that the mesh in the TVT Exact, “is not absorbed, nor is it subject to degradation or weakening by the action of enzymes.”⁴³ This is not simply inaccurate, but is false and misleading for all of the reasons stated above, including, most importantly, that Ethicon’s own internal documents and testimony from its employees confirm that the mesh degrades.

It is my opinion to a reasonable degree of medical certainty that the mesh used in TVT Exact degrades. The effect of chemical and biological degradation of the TVT Exact Prolene mesh in a woman’s tissues can lead to a greater foreign body reaction, enhanced inflammatory response and excessive scarring, which can lead to severe complications in patients, including the

⁴⁰ ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentation).

⁴¹ *Id.*

⁴² ETH.MESH.01264260 (Presentation, “Prolift+M,” P Hinoul, MD, Ethicon Pelvic Floor Expert’s Meeting – Nederland, Utrecht, May 7, 2009).

⁴³ ETH.MESH.12868147 at 8153 (original TVT Exact IFU), ETH.MESH.22129185 at 9191 (current TVT EXACT IFU).

possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Given the information available in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman's body, what the clinical implications for the woman would be and whether some women's body's would react differently to the mesh and the degradative process and its by-products.

Moreover, Ethicon failed to inform physicians or patients about the potential for degradation of the mesh and the complications that could follow. In fact, Ethicon not only failed to disclose these risks to physicians and patients, it did not accurately describe these significant risks by calling them "transitory" and by putting inaccurate statements about degradation in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their

patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of degradation of Prolene mesh in the TVT Exact. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to discuss these risks with their patients.

3. CHRONIC FOREIGN BODY REACTION

The human body has a natural and fairly predictable “host defense response” to any foreign object placed inside of it. Whether a splinter or a surgical mesh, the human body will send white blood cells to attack the invader and, if the products of inflammation cannot ward off or destroy the invader, including if the invader is anything from bacteria to prosthetic implants, the initial acute inflammatory phase is followed by a chronic inflammatory phase. Therefore, with the placement of something like a permanent surgical mesh in human tissues, there will be a chronic or permanent foreign body reaction to the implant, as well as a chronic inflammatory response by the body.⁴⁴ In fact, Ethicon Medical Directors, Piet Hinoul and Charlotte Owens, have both testified that the chronic foreign body reaction created by the body’s response to mesh can cause a severe inflammatory reaction, which can cause chronic pain, nerve entrapment, erosions, dyspareunia and the need for additional surgeries.⁴⁵

Other consultants and experts in the field informed Ethicon that there would be chronic tissue reaction to its polypropylene meshes. During a 2006 meeting at one of Ethicon’s facilities, Bernd Klosterhalfen, a pathology consultant expert for Ethicon, informed Ethicon that there can

⁴⁴ Klinge, U., et al., *Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164: 965-969; Klinge, U., *Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias*, Eur J Surg 1998, 164:951–960; Klosterhalfen, B., *The lightweight and large porous mesh concept for hernia repair*, Expert Rev. Med. Devices 2005, 2(1); Binnebosel M, et al., *Biocompatibility of prosthetic meshes in abdominal surgery*, Semin Immunopathol 2011, 33:235-243; ETH.MESH.03658577 (Biocompatibility of Ultrapro).

⁴⁵ Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

be a continuing reaction between tissues in the body and mesh for up to 20 years.⁴⁶ In addition, during a February 2007 meeting, Ethicon stated that there can be, “[E]xcessive FBR [foreign body reaction]> massive scar plate > more shrinkage.”⁴⁷

Internally, Ethicon’s scientists agreed. Dr. Holste testified that chronic foreign body reactions occurs in Ethicon’s small pore, heavyweight meshes like the Prolene mesh found in the TVT Exact.⁴⁸ In fact, Dr. Holste testified that Ethicon developed lighter weight, large pore meshes in order to minimize the complications seen with heavyweight meshes like the Prolene used in TVT Exact.⁴⁹ Ethicon employee, Christophe Vailhe, testified that there can be an excessive inflammatory reaction or foreign body reaction that would lead to mesh erosion and contraction.⁵⁰ Despite its knowledge about the problems associated with chronic foreign body reaction, Ethicon continues to use a heavyweight, small pore mesh in its TVT Exact product.

Contrary to this scientific evidence, Ethicon informed doctors in its IFU that its TVT Exact mesh was non-reactive with a minimal foreign body reaction.⁵¹ This was despite all of the internal documents and testimony discussed above from Ethicon’s Medical Affairs and Research and Development employees that chronic foreign body reaction occurs in small pore, heavyweight meshes like the Prolene mesh in TVT Exact. Moreover, as one of Ethicon’s lead engineers stated: “the foreign body reaction is not transitory – it doesn’t ever go away, but decreases over time to a minimal level.”⁵² That is, it is chronic. I have reviewed numerous pathology reports from my own patients and other physician’s patients and pathology reports reviewed in litigations describing

⁴⁶ ETH.MESH.00870466 (June 6, 2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair, Norderstedt).

⁴⁷ ETH.MESH.01218361 (Ethicon Presentation: “State of Knowledge in ‘mesh shrinkage’-What do we know”).

⁴⁸ Holste Dep. (7/29/13) 52:5-55:21.

⁴⁹ Holste Dep. (7/29/13) 51:3-53:6.

⁵⁰ Vailhe Dep. (6/21/13) 383:8-19.

⁵¹ ETH.MESH.12868147; ETH.MESH.22129185.

⁵² ETH.MESH.00211259.

foreign body reactions. Hence, the mesh potentiates a chronic, long-term inflammation. This is contrary to the express language of the TVT Exact IFU and, to this date, has yet to be corrected in that IFU.

For the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT Exact creates a chronic foreign body reaction which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon failed to inform physicians or patients about the potential for a severe, chronic foreign body response and the complications that could follow. In fact, not only did Ethicon fail to disclose these risks, it mischaracterized the risks by calling them "transitory" and by putting inaccurate statements about foreign body response in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of foreign body response of Prolene mesh in the TVT Exact. In addition,

by failing to inform physicians, Ethicon did not provide them with an opportunity to discuss these risks with their patients.

4. INFECTIONS/BIO-FILMS

The placement of midurethral slings, including TVT Exact, violates one of the most basic tenets of surgical teachings in that it is the placement of a permanent implant into the human through a “clean contaminated” surgical field, *i.e.* the vagina, which is not sterile and can never be completely sterilized, therefore, implantation through the vagina is contraindicated for every procedure and implantation.

In the TVT Exact, the weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing polysaccharide slime (biofilm), which further serves to shield the bacteria from destruction by white blood cells and macrophages.⁵³ The effect and consequences of biofilm is to increase the foreign body reaction, resulting in chronic infections, chronic inflammation, erosions, and mesh and scar contracture, and was well known to Ethicon, as evidenced by the testimony of Ethicon’s Head of Pre-Clinical, Dr. Joerg Holste.⁵⁴

Importantly, the biofilm actually serves as a protection for the bacteria surrounding the mesh fibers against the body’s host defense response (white blood cells), which are intended to destroy foreign invaders like bacteria. Thus, the weave induces the creation of a shield against the body’s defenses to the bacteria entrained in the woven mesh, inhibiting the body’s ability to fight

⁵³ Osterberg, B., et al., *Effect of Suture Materials on Bacterial Survival in Infected Wounds: An Experimental Study*, Acta. Chir. Scand 1979, 145:7 431-434; Merritt, K., *Factors Influencing Bacterial Adherence to Biomaterials*, J Biomat Appl 1991, 5:185-203; An, Y., *Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces*, J Biomed Mater Res (Appl Biomat) 1998, 43:338-348; The TVM Group: J. Berrocal, et al., *Conceptual advances in the surgical management of genital prolapsed*, J Gynecol Obstet Biol Reprod 2004, 33:577-587.

⁵⁴ Holste Dep. (7/30/13) 295:24-298:14, 411:15-414:24.

off the infective agents within the mesh. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process.⁵⁵ Daniel Burkley testified that reducing surface area could reduce the amount of chronic inflammation.⁵⁶ Additionally, the size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses leading to numerous complications.⁵⁷

There have been numerous peer-reviewed journal articles regarding secondary-mesh related infections as well as the dangers of implanting surgical mesh in a clean/contaminated field. Of note, in May of 2013, at the AUA meeting in San Diego, Dr. Shah and his colleagues reported on the “*Bacteriological Analysis of Explanted Transvaginal Meshes*,” which included explanted samples of both SUI slings and prolapse meshes. Of the 50 explants examined, 52% of those explanted due to patient complaints’ of painful mesh were infused with pathogenic organisms, 20% of those explanted due to vaginal erosions had pathogenic organism, and 83% of those explanted due to urinary tract erosions were contaminated with pathogenic organisms.⁵⁸

When polypropylene particles separate from the surface of the mesh fiber due to degradation, see *infra*, the surface area of the mesh is greatly increased thus providing even greater areas for bacterial adherence to the mesh, more elution of toxic compounds from the polypropylene, and also more of the free toxic polypropylene itself, all of which increases the inflammatory

⁵⁵ Klinge, U., et al., *Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model*, J Biomed Mater Res 2002, 63:765-771; Vollebregt, A, et al., *Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?*, Int Urogyn J 2009, 20:1345-51.

⁵⁶ Burkley Dep. (5/22/13) 371.

⁵⁷ Klinge, *supra* n. 26; Vollebregt, *supra* n. 26.

⁵⁸ Shah, K., et al., *Bacteriological Analysis of Explanted Transvaginal Meshes* (Abstract 1144).

reaction and intensity of the fibrosis.⁵⁹ This cracking of the mesh surface also provides safe harbors for infectious bacteria to proliferate.

In his periodic histopathological analyses for Ethicon of its pelvic floor explants, Dr. Klosterhalfen reported to Ethicon that, in virtually 100% of those instances in which mesh had been explanted due to erosions, he found a secondary, mesh-related infection at the tissue/mesh interface.⁶⁰ Mesh exposure and erosion cause the fibers to be further exposed to bacteria that will adhere to and colonize on the mesh surface.

Ethicon employees have testified that they were aware of these biofilms forming on the surface of the mesh.⁶¹ However, Ethicon never performed any long-term, clinical studies to determine whether the warnings given to them through the peer-reviewed literature and by their own experts and consultants were accurate, namely that mesh-related infections are real; that they cause patient injury in the form mesh erosions and recurrent, late infections; and that the transvaginal implantation through and into the non-sterile, septic vagina is below the standard of care for any surgical technique, especially one used to treat non-life threatening conditions, such as stress urinary incontinence.

Therefore, it is my opinion to a reasonable degree of medical certainty that the TVT Exact mesh is susceptible to biofilm formation due to the weave of the mesh allowing the infiltration, harboring, and protection of bacterial contaminants; the degraded mesh surface harboring bacteria; the passage through and into a clean/contaminated field; and after exposure/erosion of the mesh into the vagina or other organs, further contamination of the mesh with a multitude of vaginal flora

⁵⁹ Jongebloed, *supra*, n. 1; Sternschuss, G, et al., *Post-Implantation Alterations of Polypropylene in the Human*, J Urol 2012, 188:27-32; Clave, *supra*, at 6.

⁶⁰ ETH.MESH. 00006636.

⁶¹ Holste Dep. (7/30/13) 283:19-284:5.

that further increases the risk of harmful and recurrent infections in women. Accordingly, the TVT Exact transvaginal technique, as well as the TVT Exact mesh itself, are not safe for their intended purpose of implantation into a woman's pelvic tissues and can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Finally, Ethicon's claims in its IFU that the TVT Exact mesh may "potentiate infection" are misleading, at best. If, by the intentionally ambiguous term, "potentiate," Ethicon means "cause," then this is false for all of the reasons stated above. If by "potentiate," Ethicon means "exacerbate an existing infection," then the statement is misleading at best. Ethicon failed to warn physicians and patients that a slimy, protective biofilm could form on the mesh leading to painful erosions, recurrent, late infections and the need for mesh removal. The TVT Exact IFU contrasts sharply with the PROLENE IFU on this issue. The PROLENE IFU states as follows: PROLENE Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.⁶²

Ethicon did not to include this risk, despite that unlike hernia mesh, TVT Exact mesh is being implanted through a contaminated environment – the vagina. By failing to include this risk,

⁶² ETH.MESH.05920616 (7/20/07 Email from Chomiak, M. re Defining Light Weight Mesh).

Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

5. PORE SIZE AND FIBROTIC BRIDGING

Fibrotic bridging occurs when the fibers surrounding the pores of the mesh are too close together to allow the tissue in the pore enough room to recover from the trauma of tissue damage due to implanting a surgical prosthetic device. Pores that are large enough for good, newly-vascularized tissue tend to be filled with fatty tissue versus small pores that become filled with scarred or fibrotic tissue. In those instances, the scar forms across the pores or “bridges” from one side of the pore to the other. This can occur either due to the granulomas around the mesh fibers joining together or due to densely-formed fibroblasts between these granulomas. Either way, such bridging can lead to the creation of a rigid, scar plate that can encapsulate the mesh with scar tissue. Simply put, small mesh pores that cause fibrotic bridging turn the mesh into a solid sheet of scar tissue and there is no space or room for tissue to grow into the mesh, which is the intended purpose of the mesh. The fibrotic bridging and scar plate prevents tissue in-growth and causes complications, including, among other things, pain with the rigid mesh, shrinkage or contraction of the mesh, erosions due to mechanical irritation in the tissue of a rigid, scar- plated mesh, nerve entrapment, chronic pain and dyspareunia.

This concept is best illustrated by a DVD produced by Ethicon which features an Ethicon consultant, Dr. Todd Heniford, talking about a heavyweight, small pore mesh called Marlex used for hernia repairs.⁶³ The Prolene mesh used in TVT Exact is of heavyweight, small pore construction and, in fact, is even heavier than Marlex. Ethicon Scientists have acknowledged that

⁶³ Heniford, B.T., 2007, *The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair*, Video produced by Ethicon.

the Marlex mesh in the video is similar to the Prolene in TVT Exact in that is heavy weight small pore mesh.⁶⁴ At least one medical director, Dr. Thomas Divillio, has described the work done by Dr. Heniford and other as “material science” that would apply to both hernia and pelvic mesh products. In my opinion, this video, as well as other science and information regarding hernia meshes and other pelvic meshes is of particular relevance when discussing the TVT Exact mesh as Ethicon chose to move to large pore, light weight meshes in these areas but chose not to do so for the TVT Exact.

In the video, Dr. Heniford talks about the dangers of heavy weight, small pore meshes.⁶⁵ In fact, Dr. Heniford states, “there is no excuse for using heavy weight, small pore meshes in the human body.”⁶⁶ I have explanted numerous meshes from the TVT family and have witnessed meshes with extensive scar plating and mesh encapsulation similar to the hardened/stiffened mesh viewed in the Heniford video. In numerous emails, Ethicon employees discussed concerns regarding fibrotic bridging.⁶⁷ They have testified that the heavy weight, small pore type of mesh in the TVT Exact can lead to an increased risk of foreign body reaction, contraction of the mesh, nerve entrapment, erosions and chronic pelvic pain.⁶⁸

⁶⁴ ETH.MESH.05918776 (5/04/04 Email from Schiaparelli, Jill, Strategic Grown Subject: Marlex Experience); Batke Dep. (8/01/13) 87:12 - 88:10, 113:3-114:3, 257:23-259:13; Holste Dep (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2 185:5.

⁶⁵ Heniford Video, supra, n. 46.

⁶⁶ *Id.*

⁶⁷ ETH.MESH.04037600 (Innovations in mesh development); ETH.MESH.05920616 (7/20/07 ; Emails from Chomiak, M. to Batke, B., et al. re Defining light weight mesh); ETH.MESH.05585033 (Boris Batke Presentation – Project Edelweis – Ultrapro); ETH.MESH.05446127 (3/13/2006 Emails from Holste, J. to Engel, D., et al. re Mesh and Tissue Contraction in Animal – “Shrinking Meshes?”); ETH.MESH.05475773 (2/09/2007 Boris Batke, Ethicon R&D, Presentation: *The (clinical) argument of lightweight mesh in abdominal surgery*); ETH.MESH.04015102 (3/1/12 Email from Batke, Boris to Mayes, C. re AGES Pelvic Floor Conference-Gala Dinner Invitation); ETH.MESH.04037600 (3/15/12 Boris, B. PowerPoint Presentation, *Innovations in Mesh Development*, Melbourne AGES 2012).

⁶⁸ Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste Dep. (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

In other emails, when discussing these concepts, Ethicon's World Wide Marketing Director for General Surgery, Marty Chomiak, states that "... we want to avoid 'bridging', therefore we think large pores are better than small . . ." ⁶⁹ Ethicon also had information and scientific knowledge regarding superior mesh designs to prevent fibrotic bridging and scar plating. Specifically, Ethicon also had scientific knowledge that light weight, large pore mesh could decrease the likelihood of foreign body reaction, fibrotic bridging and scar plating. ⁷⁰

Despite having clinical knowledge of the importance of pore size to successful outcomes, and dozens of emails about the importance of pore size, Ethicon's person most knowledgeable about pore size testified that Ethicon does not manufacture its mesh to a specific pore size. Dan Smith testified as follows:

Q: Does Ethicon have a validated test method to determine the pore size of its TVT mesh?

A: We determine the pore size by courses and wales and that is how it's done. So the courses and wale count is a validated test method.

Q: And I'm talking about pore size. Does Ethicon have a validated test method to determine its pore size for its mesh?

A: The construction of the mesh is -- does not have a pore size requirement. ⁷¹

In fact, Ethicon does not even have a test to measure the pore size of its mesh. Dan Smith testified:

Q. Mr. Smith, does Ethicon have a validated test to describe the pore size of its TVT meshes microns? Yes or no.

A. No.... ⁷²

Despite this information that it did not measure pore size or manufacture its mesh to a specific requirement, Ethicon repeatedly stated in advertising and marketing materials that its mesh was "large pore." For example, in one brochure, Ethicon promotes the mesh used in the TVT

⁶⁹ ETH.MESH.05920616 (7/20/07 Email from Chomiak, M. re Defining Light Weight Mesh).

⁷⁰ Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste (7/29/13) 51:3 - 53:6, 55:22 - 57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

⁷¹ Smith Dep. (2-3-14) 729:1 to 729:12.

⁷² Smith Dep. (2-3-14) 779:5 to 779:8.

family of products (including TVT Exact) as the “Largest pore size” of any of its competitors, listing the size as 1379 um.⁷³ However, given that Ethicon has no verified methodology to measure pore size, Ethicon had no scientific basis upon which to base these statements. In fact, in internal documents, Ethicon scientists described PROLENE mesh as small pore: “Standard Mesh PROLENE small pores area weight 105 g/m2.”⁷⁴ One Ethicon Engineer measured a mesh and determined that there were two pore sizes in the mesh, a “major” and “minor” pore. “There are two distinct pore sizes in the PROLENE 6 mil mesh (TVT). The major pore is about 1176 um.... The minor pore is about 295 um.”⁷⁵ Certainly, neither of these pores was 1379 um, and the minor pore was substantially smaller.

In summary, for the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT Exact causes fibrotic bridging in the body, resulting in an increased inflammatory response leading to a multitude of injuries, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can be chronic, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon’s TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to fibrotic bridging. Ethicon failed to warn physicians and patients that fibrotic bridging could occur

⁷³ ETH.MESH.00349508 at 9510.

⁷⁴ ETH.MESH.04941016.

⁷⁵ ETH.MESH.00584175 (Ex. T-3583); ETH.MESH.00584179 (Ex. T-3581).

leading to painful erosions, recurrent, late infections, nerve injury and the need for mesh removal. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

6. MESH CONTRACTURE/SHRINKAGE

Mesh contracture or shrinkage is an event that takes place after the implantation of mesh and relates to the wound healing process that occurs after the surgical trauma of implanting a foreign body made of polypropylene in the sensitive tissues of the vagina and pelvis. By 1998, polypropylene mesh was known to contract or shrink 30-50%.⁷⁶ These findings were later confirmed in numerous papers, such as those by W Cobb and his colleagues – one of whom was Dr. Henniford (referenced above).⁷⁷ This also showed that heavier weight meshes like TVT Exact led to greater amounts of contraction. The works of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents. Contraction or shrinkage has been shown to draw nerves close to the midurethral sling mesh both in the transobturator application⁷⁸ and for retropubic application.⁷⁹ Furthermore, contraction or shrinkage is closely related to the pore size and weight of the mesh. Small pore, heavy weight mesh leads to fibrotic bridging which leads to scar plates, mesh encapsulation and shrinkage or contraction of the mesh, which is compounded by the shrinkage effect associated with the normal wound healing process already occurring in the tissue.

⁷⁶ Klinge, U, *Shrinking of Polypropylen Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.

⁷⁷ Cobb, W., et al., *The Argument for Lightweight Polypropylene Mesh in Hernia Repair*, Surgical Innovation 2005, 12(1):T1-T7.

⁷⁸ Corona, R., et al., *Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy*, J Min Invas Gynecol 2008, 15:3 262-267; Parnell, B.A., et al., *Genitofemoral and Perineal Neuralgia after Transobturator Midurethral Sling*, Obstet Gynecol 2012, 119:428-431; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Intl Urogyn J, 2009, 20:893-6; Tunn, R, *Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in Women with Cystocele or Rectocele*, Ultrasound Obstetrics Gynecol 2007, 29:449-452.

⁷⁹ Heise, C.P., et al., *Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?*, J Am Coll Surg

This phenomenon of shrinkage and its relation to the design of the pores as well as the consequences to the patient were illustrated in an email by Ethicon Scientist Joerge Holste in a March 13, 2006 email discussing a paper he authored entitled “Shrinking Meshes?”⁸⁰ In his email, Dr. Holste states “this was our scientific statement on mesh shrinkage: Basically, small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage during maturation of the collagenous tissue. See my presentation about biocompatibility.”⁸¹ In addition, in a presentation by Boris Batke, Associate Director R&D, he states heavier-weight polypropylene mesh results in mesh contraction of 33%.⁸² In an email dated November of 2002, related to a discussion of mesh used in a TVT product, Axel Arnaud, one of Ethicon’s medical directors, used 30% shrinkage of the mesh as a “rule of thumb.”⁸³ At an Ethicon expert meeting in Norderstedt, Germany in 2007, an Ethicon employee presented a PowerPoint entitled “Factors Related to Mesh Shrinkage” in which all of these issues were clearly laid out.⁸⁴

Mesh shrinkage was known by Ethicon as early as 1998 in published work by Ethicon’s then consultants, Uwe Klinge and Bernd Klosterhalfen.⁸⁵ They noted in these early papers that all polypropylene meshes shrink 30-50%. This was restated in later works by W Cobb and his colleagues⁸⁶--one of which was Dr. Heniford (referenced above). The words of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents and thus, Ethicon was

⁸⁰ ETH.MESH 05446127, *supra*, n. 34.

⁸¹ *Id.*

⁸² ETH.MESH 05479717 (3/1/11 Boris Batke, Ethicon Associate Director R&D, Presentation: Ethicon Polypropylene Mesh Technology).

⁸³ ETH.MESH 03917375.

⁸⁴ ETH.MESH. 02017152 (Nordestadt Expert’s meeting 2007); ETH.MESH.01782867 (Factors Related to Mesh Shrinking).

⁸⁵ Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969

⁸⁶ ETH.MESH.07455220.

well aware of these findings regarding the shrinkage or contraction of polypropylene meshes in vivo. Ethicon was further aware that heavier weight meshes led to greater amounts of contraction.

It is my opinion to a reasonable degree of medical certainty that as a result of work with internal and external experts and consultants in the late 1990s, multiple internal documents and articles, and the scientific literature as a whole, that Prolene mesh used in TVT Exact not only could, but would shrink and contract, and that this shrinkage could lead to painful complications in women implanted with TVT Exact, such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

As a result, the polypropylene in Ethicon's TVT Exact mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women, and Ethicon failed to warn physicians and patients of the possibility of shrinkage and contraction and the adverse outcomes that could occur as a result.

7. ETHICON HAD LIGHTER WEIGHT, LARGER PORE MESHES AVAILABLE

Ethicon did not change the Prolene mesh in its TVT Exact device despite having better and safer options available for economic reasons. As early as May of 1997, Ethicon knew that the Prolene mesh was not ideal for use in vaginal tissues.⁸⁷ However, Ethicon believed that continued use of the Prolene mesh gave the company an economic and competitive advantage in marketing the product because they could continue to use the existing clinical data on the product to market

⁸⁷ ETH.MESH.12006257

the device, while if the mesh was changed, the existing clinical data would be obsolete.⁸⁸ Dr. Brigitte Hellhammer testified that despite having incorporated the use of the lightweight, large pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse, the Ultrapro was never used by Ethicon in a device used for the treatment of stress urinary incontinence largely because the company wanted to continue to rely on the Ulmsten/Nilsson series of studies on 130 patients performed with the TVT device.⁸⁹ Dr. Arnaud also confirmed that the company did not want to change anything with the mesh because of the exiting clinical data on the product.⁹⁰ It is my opinion to a reasonable degree of medical certainty that Ethicon was negligent in failing to correct the defects in the TVT Exact mesh as the company had knowledge of the defects and failed to correct the defects with products and solutions that were already available to the company because it put its economic interests above the safety of patients.

B. THE TVT EXACT IFU LACKED ALL KNOWN RISKS AND WAS INACCURATE.

The purpose of the IFU is for a medical device manufacturer to provide physicians with the information necessary for them to make decisions regarding the used a medical device for a particular patient. In addition, the IFU should disclose adverse reactions and risks known to the medical device manufacturer to the physician so that the risks can be relayed to the patient and an informed decision regarding the use of the product can be reached. Throughout my education, training, surgical and clinical practice, I have reviewed numerous IFUs for a variety of products, including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with a device. I have extensive

⁸⁸ ETH.MESH.03911107

⁸⁹ Hellhammer Dep. (9/11/13)

⁹⁰ Arnaud Dep. (7/19/13) 36:15-37:3

clinical experience with IFUs and instructing patients about the adverse events/risks contained in the IFU. Similar to Medical Directors, Dr. Martin Weisberg and Dr. David Robinson, I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs, and consenting patients regarding IFUs, including Ethicon's own pelvic mesh products including the TVT line and Prolift.

Catherine Beath, Ethicon's former Vice President of Quality Assurance and Regulatory Affairs, testified that "physicians should be made aware of all the significant safety risks associated with the product in the IFU."⁹¹ And, "a reasonably prudent medical device company would continually update the label consistent with developing data and information that becomes known to the company" when it is appropriate.⁹² Similarly, former Medical Director Dr. David Robinson testified that the warnings and adverse event section of the IFU should include all significant risks and complications related to the procedure and the mesh.⁹³ According to Dr. Robinson, a device manufacturer must include this information because you want to make sure the doctors have all the information they need to adequately inform patients who are deciding to use the product.⁹⁴ According to Ethicon Medical Director Dr. Martin Weisberg, the goal of the IFU is to communicate the most important safety risks attributable to the TVT device and that an IFU should never exclude known hazards or complications.⁹⁵ Dr. Weisberg also believes that an IFU should not knowingly underestimate the risks of using the product.⁹⁶ And, if an IFU excludes known complications or understates the risks, it "fails in one of its principal purposes."⁹⁷

⁹¹ Beath Dep. (7/12/13) 592:7-11.

⁹² Beath Dep. (7/11/13) 198: 8-13.

⁹³ Robinson Dep. (9/11/13) 238:12-25.

⁹⁴ Robinson Dep. (9/11/13) 239:1-11.

⁹⁵ Weisberg Dep. (8/9/13) 659:19-660:15.

⁹⁶ *Id.* at 960:13-16.

⁹⁷ *Id.* at 961:10-17.

1. THE IFU DOES NOT INCLUDE ALL KNOWN RISKS.

As noted above, Ethicon did not include the proper information concerning the dissection in the original IFU. There were also numerous other potential risks that were not included in the IFU at launch. If you compare the adverse reactions/risks in the TVT Exact IFUs to the adverse reactions/risks that were available and known to Ethicon at the time of the launch of TVT Exact, it is clear that there are numerous adverse events absent from the IFU. For example in the TVT Exact IFU at launch, the Adverse Reactions/Risks section read as follows:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.⁹⁸

Despite only listing the above adverse reactions/risks, it is clear from the testimony of Senior Ethicon Employees in both the Medical Affairs and Regulatory Affairs that every adverse reaction/risk that Ethicon has scientific knowledge of today, it had scientific knowledge about at the time the TVT was first sold in and certainly in 2010 when the first TVT Exact was sold, marketed and launched. This is most evident in Medical Director Marty Weisberg's recent deposition regarding the 2015 updated IFU.⁹⁹ In 2015, Ethicon updated its IFUs in response to requests from Health Canada.¹⁰⁰ The Adverse Reactions section now states as follows:

ADVERSE REACTIONS

⁹⁸ ETH.MESH.12868147 at 8153.

⁹⁹Weisberg Dep. (11/13/15) 361:9-379:16.

¹⁰⁰ Weisberg Dep. (11/12/2015) 23:21-24:7.

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory location irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As will all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentially an existing infection.
- Over-correction, i.e., too much tension applied to the mesh implant, may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain.
- Voiding dysfunction.
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and /or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma
- One or more surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge Incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause or discomfort to the patient's partner during intercourse
- Death¹⁰¹

Despite this update, Ethicon still chose to exclude from the list certain information of which it was aware at the launch of the product. Medical Director, Piet Hinoul also testified that Ethicon understood the following adverse events occurred from the time the TVT was first sold, years before the first TVT Exact was sold, yet none of these were in the TVT Exact IFU at launch:

Erosions through vaginal epithelium
Infection
Pain
Urinary Problems

¹⁰¹ ETH.MESH.22129185 at 9190.

- Erosions that could decrease patient's quality of life
- Dyspareunia
- Need for additional surgeries
- Need for the removal of device
- Urinary Tract Infections
- Dysuria
- DeNovo Urgency
- Mesh Exposure
- Fistula Formation
- Hematoma
- Abscess Formation
- Narrowing of vaginal wall
- Erosion which can occur any time in future
- Contracture of mesh causing pain
- Complications making it impossible to have sexual relations
- Worsening Incontinence

In addition, Ethicon failed to include significant risks in its IFU related to the Prolene polypropylene mesh, including association with tumor formations and that the mesh can degrade, shrink and contract. The IFU also fails to include risks associated with the Prolene mesh, including excessive rigidity, chronic foreign body reaction, fibrotic bridging, and infections/biofilms.

Dr. Weisberg also testified that Ethicon did not include: “permanent, lifelong, worsening and debilitating pain,” lifelong risk of surgical repairs for erosions, “severe or chronic inflammation,” fibrotic bridging, that the product can degrade, or cause severe erosion.¹⁰² In addition, former Medical Director, Dr. David Robinson, testified that Ethicon never informed physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, and that patients could endure lifelong severe pain or dyspareunia/painful sex. This is true despite, as discussed above, Ethicon had scientific knowledge of the risks at the time of launch.

¹⁰² Weisberg Dep. (8/9/13) 968:12-972:21.

2. THE IFU INACCURATELY PORTRAYED RISKS

In addition to excluding certain known risks, Ethicon significantly downplayed the risks that it actually listed in its IFU. This is especially true with respect to erosions. On the topic of erosions, in the Adverse Event/Risks section in the TVT Exact IFU, in place from the time of launch until 2015, it states:

Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.¹⁰³

In 2015, the new IFU was updated and this section was broken up into bullet points with little significant information added:

- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign response may occur. This response could occur result in extrusion, erosion, exposure, fistula formation and/or inflammation.¹⁰⁴

This language significantly downplays, and continues to downplay, the permanent nature of erosions and suggests to physicians that erosions are a “transitory” or temporary problem. As shown in an email exchange between Ethicon’s Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., Ph.D and Bryan Lisa in the Regulatory Affairs Department, it was clear that the adverse events were not “transitory.” Chen wrote, “Pardon me again, from what I see each day, these patient experiences are not “transitory” at all.”¹⁰⁵

Ethicon also had scientific evidence that erosions could occur many years after implantation of the device. In Minutes from June 22, 2001 Scientific Advisory Committee on Pelvic Floor Repair, it was a “Consensus: Erosion is a risk. Erosion, possibly an infection response. Typically seen by 3 mos, usually by 6-12 mos. Can present late, 3 years. To vagina-

¹⁰³ ETH.MESH.12868147 at 8153.

¹⁰⁴ ETH.MESH.22129185 at 9190.

¹⁰⁵ ETH.MESH.04093125 (1/29/09 Email between Meng Chen and Bryan Lisa).

not a good situation. To bladder, urethra or rectum-a very bad situation.”¹⁰⁶ “There have been reports of erosions into the urethra that are not picked up until months even years after the procedure.”¹⁰⁷ In October 2002, Medical Director Dr. Martin Weisberg was involved in email exchange with European Science Director Axel Arnaud about downplaying risks with respect to erosions. Specifically, Dr. Arnaud suggested to Dr. Weisberg that Ethicon needed “to be more elusive” when discussing potential complications like erosions.¹⁰⁸

According to Medical Director Dr. Martin Weisberg and former Medical Director Dr. David Robinson, Ethicon never disclosed or warned doctors or patients in IFUs or Patient Brochures that the use of TVT Exact slings can cause lifelong risk of erosions.¹⁰⁹ Despite the fact Ethicon had scientific feedback from one of its own doctors that experiences were not transitory and that she had concerns about the IFU and the transitory language, Ethicon never informed physicians or disclosed it in its IFU.

In summary, Ethicon did not fully inform physicians about numerous adverse reactions/risks associated with the TVT Exact despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold. As a result, physicians were unable to fully consent and inform patients of the risks associated with the TVT Exact. In addition, some risks included by Ethicon in the IFU are mischaracterized to minimize the actual risk. To a reasonable degree of medical certainty, this prevented physicians and patients the ability to make an informed choice regarding the use of the TVT Exact.

¹⁰⁶ ETH.MESH.02089392.

¹⁰⁷ ETH.MESH.04099233 (September 24, 2008 email from Melissa Day to Meng Chen and others).

¹⁰⁸ ETH.MESH.03910175-03910177.

¹⁰⁹ Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7.

C. ETHICON FAILED TO TEST THE TVT EXACT.

A reasonable and prudent medical device manufacturer should have adequate safety data to support its products before urging surgeons to use them permanently on patients.¹¹⁰ Before the TVT Exact was launched on the market, Ethicon did not have any clinical data showing the TVT Exact was safe and effective.¹¹¹ As discussed above, there was also no clinical data showing that the laser cut mesh was shown to be safe and effective. Carl Nilsson, one of the inventors of the TVT and Ethicon KOL, and Christain Falconer, another KOL, told Ethicon in early 2008 that it “is impossible and incorrect to say or assume that Laser Cut would be the same as mechanically cut. Comparative in vivo studies is a necessity to determine the differences. Theoretical calculations are not enough as evidence.”¹¹² Despite this and the design modifications made, Ethicon chose to leverage its long term data from the TVT in order to speed the TVT Exact to market without gathering any clinical data.¹¹³

¹¹⁰ Cornelis et al., *The introduction of mid-urethral slings: an evaluation of literature*, Int Urogynecol J (2014) “clinicians and their professional organizations should only choose devices that have adequate clinical data to support their efficacy and safety”; Abrams et al., *Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe*, European Urology 60 (2011) 1207-1211 “Manufacturers’ responsibilities should include the following tasks: testing the device thoroughly, including carrying out appropriate clinical trials, before placing on market.” “The need for randomized controlled trials (RCTs) at an early stage of development of any new device, with significant new features compared with existing tapes, was felt be essential. The clinicians expressed regret about the number of low-quality studies, usually case series, published in the literature.” Kane, et al, *Midurethral Slings for Stress Urinary Incontinence*, Clinical Obst. and Gyn., Vol 5, No. 1, 124-135. (“Surgeons should be skeptical and wary of new products that lack human study data.”); Deprest et al, *The need for preclinical research on pelvic floor reconstruction*, BJOG, 2013. (“Often complications are caused by properties of materials that haven’t been evaluated before clinical use.”); Nilsson, *Creating a gold standard surgical procedure: the development and implantation of TVT*, Int. Urogyn. 2015, Dwyer, *Editorial The 75% rule: all stress incontinence procedures are alike*, Int. Urogyn. 2011; H. Azaïs et al. / European Journal of Obstetrics & Gynecology and Reproductive Biology 178 (2014) 203–207; (“Trials incorporating large amounts of patients are needed...”); Shepherd et al., *Uniaxial biomechanical properties of seven different vaginally implanted meshes for pelvic organ prolapse*, Int Urogynecol J (2012) 23:613–620 (“Despite its widespread acceptance and use, synthetic meshes have had little regulatory oversight”); Fiener et al, *Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systemic review*, BIOG 2009;116:15-24.

¹¹¹ ETH.MESH.09199174.

¹¹² ETH.MESH.16416003.

¹¹³ ETH.MESH.1431484; 01678349.

The TVT Exact should not have reached the market without clinical studies on safety, efficacy, or adverse outcome data.¹¹⁴ Ethicon wanted the TVT Exact on the market before a competitor's sling was launched in order to maintain control of the retropubic market and did so by relying on the TVT's data and submitting a Special 510k instead of a Traditional 510k.¹¹⁵ As noted in the powerpoint, this saved Ethicon 90 days, roughly 3 months, in waiting for the FDA to review the submission.¹¹⁶

In an editorial from the International Urogynecology Journal, Peter Dwyer wrote that he would not use the TVT Exact because of the lack of clinical data. He had been informed by a hospital that it was going to replace the TVT with the TVT Exact. When Dwyer asked a company representative about the differences between the TVT and the TVT Exact, the "company representative could not provide [him] with any information or on the effectiveness and safety generally, not even retrospective studies."¹¹⁷

Ethicon has continued to market the TVT Exact using the TVT data which is misleading to physicians and patients. In a 2013 email, Scott Finley writes to certain sales employees asking everyone to review their "at-risk business" noting that "these users tend to believe in 'data' so our product [the TVT Exact] is well-backed with 11.5 years of clinical evidence with a greater than 97% success rate."¹¹⁸ Interestingly, at the top of the email chain, there is a follow-up email from a sales representative, noting that they cannot use the same data because it is a different mesh.¹¹⁹ However, Ethicon continued to do so. In one sales aid, Ethicon highlights that the "Gynecare TVT

¹¹⁴ Chapple, et al., *Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward*, J Eururo.2013.06.045.

¹¹⁵ ETH.MESH.1431484.

¹¹⁶ *Id.*

¹¹⁷ Dwyer, Peter L., *The 75% rule: all stress incontinence procedures are alike*; Int Urogynecol J (2011) 22:769-770.

¹¹⁸ ETH.MESH.08422124

¹¹⁹ *Id.*

Exact is built upon 12 years of retropubic success.”¹²⁰ In another, it claims that the TVT Exact is “built upon 17 years of Gynecare TVT success.”¹²¹ It is of particular importance that Ethicon’s own expert, Dr. Michael P. Woods, says the long term data on which Ethicon relies for selling the TVT Exact relates to mechanical cut mesh and not laser cut and he could not say that the data is transferrable to show that the laser cut should be considered the gold standard also.¹²² Thus, Ethicon’s reliance on the mechanical cut, long term data of the TVT cannot be used to support the safety and efficacy of the TVT Exact.

It is my opinion that Ethicon failed to test the TVT Exact and mislead physicians and patients into thinking that the TVT Exact had been studied and determined to be safe and efficacious in order to drive sales of the product.

D. ETHICON WITHHELD MATERIAL FACTS ABOUT THE TVT DATA IT RELIED UPON.

Since the TVT was first launched, Ethicon has sent materials in various forms to physicians promoting long term follow up data on the original cohort of patients implanted with the TVT from 1995-1996.¹²³ Ethicon continued to cite to this data in all of its TVT materials. In addition, the materials tout low complication rates related to various adverse reactions, including erosions. These materials include press releases, marketing brochures and email blasts.

The long term data primarily relied on by Ethicon throughout these materials relates to the Ulmsten/Nillson studies. These studies were originally started by Dr. Ulmsten, the inventor of the TVT, and continued by Dr. Nillson after Dr. Ulmsten’s death. Prior to selling the TVT to Johnson

¹²⁰ ETH.MESH.01290213

¹²¹ ETH.MESH.12844213.

¹²² Woods Dep. (10/5/2015) 149:11-24.

¹²³ ETH.MESH.0015598, ETH.MESH.00658058, ETH.MESH.01186068, ETH.MESH.02236784, ETH.MESH.02237103, ETH.MESH.03459211, ETH.MESH.05183409, ETH.MESH.00339437; ETH.MESH.05794787.

& Johnson, Dr. Ulmsten owned a company called Medscand. As discussed more fully below, Johnson & Johnson hired Dr. Ulmsten and Medscand to conduct studies related to the TVT. To this day, Ethicon relies heavily on these studies and uses them in numerous promotional materials despite the fact that Ethicon never disclosed to physicians the potential conflict of interest and inherent bias that exists due to Dr. Ulmsten's relationship with Ethicon and Johnson & Johnson. In addition, Ethicon never disclosed to physicians that the device used in the original Medscand study was different than the TVT device. It is important to physicians using the TVT that the data in these types of promotional materials is accurate, unbiased and that physicians are informed about any potential conflicts of interest in the data contained within the materials. In other words, physicians rely on Ethicon to provide fair and balanced information and to ensure that physician have been given all the data and not just the positive press release data.

Despite using the Ulmsten data to promote the TVT, Ethicon never disclosed to physicians the bias and inherent conflict of interest related to the Ulmsten data. Specifically, in its promotional materials, Ethicon (Johnson and Johnson) never informed physicians about its relationship and contracts with Professor Ulmsten and his company Medscand. It is clear from the contracts that the publications and data from Dr. Ulmsten were contracted for hire by Johnson and Johnson International.¹²⁴

The License and Supply Agreement between Johnson and Johnson International and Medscand (Ulmsten's Company) dated February 13, 1997, states in section 3.6 Milestone Payments:

Johnson and Johnson International (JJI) shall pay shall pay to Medscand the following payments (b). A payment in the amount of \$400,000.00 due on February 28, 1997; provided, however, that in the event that Clinical Trials as specified in

¹²⁴ ETH.MESH.08696085 at 085-6134.

Exhibit C have not been completed by such date, then such amount shall not be due until the completion of the Clinical Trials.¹²⁵

Under Exhibit F, Consulting Agreement with Professor Alf Ivar Ulmsten, section 4 Confidential Information Rights to Inventions and Copyrights (B) it states:

Any copyrightable work whether published or unpublished created by supplier Dr. Ulmsten directly as a result of or during the performance of services herein shall be considered a work made for hire, to the fullest extent permitted by law and all rights, titles and interest herein, including worldwide copyrights shall be the property of the company as the employer and party specially commissioned said work.¹²⁶

Finally, in Exhibit C, Clinical Trials, it states:

The results of clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article published in the Int. Urogynecol J 1996-7:81-86 by U. Ulmsten, et.al., with regards to the following items: Safety 1.1, preoperative complications 1.2, post operative complications 1 year from operation 2. Efficacy. Second Long term results over 1 year from operation do not show a deterioration of rates significantly different from those of the standard suburethral slingplasties. It is assumed that from 12 – 60 months a gradual decrease in efficacy of 5% is normal. 3. No significant numbers of unexpected i.e. not addressed in the original article published in the Int. Urogynecol J 1996 81-86 by U. Ulmsten et.al. procedure related i.e. not addressed in the review article published in the Int. Urogynecol J 1994: 228-239 by G. N. Ghomiem et.al. complications appear at any time in the postoperative course.¹²⁷

In total, Dr. Ulmsten stood to gain millions of dollars for the 6 papers that he published on the TVT device. In addition, the results of those studies would be found acceptable for payment only if they did not differ from the parameters set by Johnson & Johnson regarding complications and efficacy. The Ulmsten studies have an inherent conflict of interest and bias as they were “made for hire” and standards were set by Johnson & Johnson. As set forth above, if Dr. Ulmsten did not meet the standards set forth by Johnson & Johnson, he did not receive substantial payments for the

¹²⁵ ETH.MESH.08696091.

¹²⁶ ETH.MESH.0869116.

¹²⁷ ETH.MESH.08696132.

“studies.” As a result of this relationship, there is a clear conflict of interest and potential for enormous bias issues.

The conflict of interest and bias created by the relationship between Ethicon and Dr. Ulmsten was acknowledged by Dr. Axel Arnaud, Ethicon’s European Medical Director, in a recent deposition. Specifically, Dr. Arnaud testified that such an agreement like the one discussed above between Dr. Ulmsten and Johnson & Johnson creates a potential conflict of interest.¹²⁸ Dr. Arnaud also acknowledged that when Johnson & Johnson enters into this type of agreement with a physician or his company and the study is published, there “certainly” needs to be a disclosure of the relationship.¹²⁹ Additionally, Former Ethicon Medical Director, Dr. David Robinson, testified that in his experience working in the industry for medical device manufacturers, it is best that potential biases be disclosed.¹³⁰ He also testified that if publications from somebody like Ulmsten or Nilsson about safety and efficacy are being published, it is best if they disclose that they have a financial bias or conflict of interest.¹³¹ In fact, in an April 2009 email exchange with Medical Director Piet Hinoul about a physician who, like Ulmsten, is a consultant and inventor for competitor Boston Scientific, Dr. Robinson states that that situation presents “enormous bias issues.”¹³² Despite two of its medical directors testifying that the relationship between Ulmsten and carried over to Nilsson presents a conflict of interest and bias, Ethicon has never disclosed this information in its promotional pieces. This is information physicians and patients have a right to know so that a proper informed decision regarding the value of the data in the studies and the use of the product can be made.

¹²⁸ Arnaud Dep. (7/20/13) 497:24-501:21, 509:8-17.

¹²⁹ Arnaud Dep. (7/20/13) 514:17-515:1.

¹³⁰ Robinson Dep. (9/11/13) 214:15-21.

¹³¹ Robinson Dep. (9/11/12) 215:8-13.

¹³² ETH.MESH.03259439; Robinson Dep. (9/11/13) 219:6-220:10.

Aside from never disclosing to physicians the underlying conflict of interest and bias of the Ulmsten studies in its promotional pieces, Ethicon also never informed them about other problems with the data, including incomplete data on the original cohort, data incorrectly reported and erosion rates underreported. In the original 510k submission for TVT Classic, Ethicon used Medscand data from the Scandinavian Multicenter Study.¹³³ The report shows that 12 month follow was obtained for 90 of the original 131 patients, without explanation of why there was a loss of 41 patients from the study. The study also describes a complication of wound infection: “while the vaginal infection required surgical intervention with resection of exposed mesh.” This represents a vaginal mesh erosion/extrusion/ exposure and needs to be reported as such. However, when the paper was published (Ulmsten, Int Urogynecol J 1998), the paper states that there was no defect healing and no tape rejections. It further misrepresents the outcome for this patient as “The patient with the wound infection had vaginal atrophy. After minimal vaginal wall resection and effective local estrogen treatment she healed without further intervention. There was no tape rejection.”

If Ulmsten had reported a mesh erosion/extrusion/exposure with mesh excision in his study, it would not have been acceptable under Exhibit C of his consulting contract for payment of the \$400,000.¹³⁴ This demonstrates that the results of this paper were potentially biased by the payment Ulmsten would receive for favorable data and should discount the data. At the very least, Ethicon should have informed physicians about the relationship between Ethicon and the Ulmsten studies.

¹³³ ETH.MESH 00371587.

¹³⁴ ETH.MESH 08696132.

In one of the Nilsson studies, Dr. Nilsson describes four patients on “anticholinergics” (Int Urogynecol J 2008 Table 3). They conclude: “It is also encouraging to see that no late adverse effects of the polypropylene tape material was found and that erosion of the tape into adjacent tissue did not occur.” However, this statement cannot be made for 4 patients who are on pharmacotherapy without a cystoscopy, which was not performed in the 11 year follow-up study. Dr. Raz’s review of the literature found multiple cases of urethral erosions in a large series with TVT.¹³⁵ There have also been multiple case reports attesting to the fact that urethral erosion does occur specifically with Gynecare TVT products.¹³⁶ To imply that urethral erosion does not occur is not giving physicians fair and balanced information about the true incidence of urethral erosions with TVT products.

Later, Nilsson publishes the 5 year follow-up of this cohort.¹³⁷ He describes the cohort: “a prospective open multicenter trial was conducted in the Nordic countries at the beginning of 1995. The short-term results were published in 1998.” This implies that these are the same patients as published in 1998. It is interesting or an incredible coincidence that the exact number of patients receiving 12 months of follow-up in the Medscand publication (90) was the exact number being described in the 5 year study. There is again no mention of the outcome of the other 41 patients from the original cohort. Another interesting detail in the 5 year study is that the original number of centers used for the study (6) was now down to 3, again without explanation. The 5 year report

¹³⁵ Karam 2003, Hammad 2005.

¹³⁶ Sweat, S., et al, *Polypropylene Mesh Tape for Stress Urinary Incontinence: Complication of Urethral Erosion and Outlet Obstruction*, J Urology 2002, 168:144-146; Gerstenbluth, R.E., et al, *Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling*, J Urol. 2003, (2 Pt 1) 170:525-6; Vassallo, B.J., et al., *Management of Iatrogenic Vaginal Constriction*, Am J Obstet Gynecol 2003, 102(3):512-20; Haferkamp, A., et al., *Urethral Erosion of Tension-Free Vaginal Tape*, J Urol 2002, 167(1): 250.

¹³⁷ Ulmsten data; Nilsson, Int Urogynecol J 2001.

does describe the original patient with the wound infection but again fails to mention she had mesh excised, “1 case (1.1%) of infection of operating site was observed.”

In 2006, Dr. Nilsson published a different study on long term outcome of patients with TVT.¹³⁸ He describes his new patient population: “A multi-center study comprising only carefully selected primary cases revealed a promising cure rate of 85% after 5 years (reference his 5 year study) and 81% at 7 years.”¹³⁹ These two papers are the subject of many press releases and marketing brochures, but they never described that these were carefully selected patients. “To our knowledge, the long-term effect and effectiveness of the TVT procedure has not yet been studied in an unselected patient group. We earlier reported 16-month follow-up results of a general patient group referred to a tertiary medical unit and comprising primary, recurrent, mixed, and low pressure urethra cases. In the present study, we report the long-term results in the same above-mentioned group.” They describe a 3.1% mesh “visualized” rate, half of which needed surgical resection. These results, more representative of what one would see in a normal practice, is never mentioned in press releases or marketing documents.

Conversely, when Ethicon receives adverse information, it does not make it into the promotional pieces. Dr. AC Wang's abstract, “Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report” was used in the original 510k submission in October of 1997 as support for FDA clearance of the TVT.¹⁴⁰ However, when Dr. Wang reported that he had 25 cases of “failure of vaginal healing considered by him to be potential tape rejection...in each case the revision failed within 2 weeks, requiring further surgery to excise mesh and repair the

¹³⁸ Kuuva, N., et al., *Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women*, Acta Obstetrica Gynecologica Scandanavica 2006, 85:4 482-87.

¹³⁹ Nilsson, Obstet Gynecol 2004.

¹⁴⁰ ETH.MESH.00371551.

vaginal wound,” this important information never made it into the marketing materials or press releases.¹⁴¹

The long-term follow-up data (Ulmsten/Nilsson data) used by Ethicon to promote the lack of risk of TVT is spurious at best. We have incomplete data on the original cohort, data that is falsely reported, original sites that were excluded without explanation and a lead investigator who had a significant relationship and financial incentive to reach certain results with the data. This is the same data which is now used repeatedly in promotional and marketing materials sent to physicians.

E. ETHICON’S FIRST MARKETED TVT EXACT’S TROCAR AND SHEATH WERE ALSO DEFECTIVELY DESIGNED.

The TVT Exact was marketed as an improved TVT. Before it was given the name, TVT Exact, it was called the “TVT-RR” meaning “Retropubic Refresh.” While many of the characteristics between the products are the same, the TVT Exact included several changes, such as: the dimensions of the trocar shaft, from 5mm to 4.2mm, and the packaging configuration, including the sheath.¹⁴² Of note, the smaller trocar was designed to enable the physician to deliver a precise placement while reducing the penetration force.¹⁴³

The TVT Exact was launched during the summer of 2010. Within the first year of its launch, Ethicon began receiving complaints regarding the trocar “tips” bending and breaking off.¹⁴⁴ As a result, Ethicon began an investigation. Reports in late 2011 showed tips “bent at 30 degrees,” metal portions exposed due to cracking, physicians having to use more than one TVT

¹⁴¹ ETH.MESH.00409675.

¹⁴² ETH.MESH.00020231 at 0245 and 0258-0259.

¹⁴³ ETH.MESH.1431484.

¹⁴⁴ ETH.MESH.03573067.

Exact in an operation, and tips breaking.¹⁴⁵ It was also noted that well-trained physicians who were experiencing these issues also.¹⁴⁶

In an email from May 2012, a sales manager noted that the bending and breaking TVT Exact plastic sheath tips is a “major issue we face” and sought advice from Ethicon on how to handle.¹⁴⁷ Ethicon responded that a cadaver lab had been conducted, the results of which lead “to the conclusion that the procedures were not performed in compliance with the IFU.”¹⁴⁸ ¹⁴⁹ Thus, Ethicon would not look into the issue further, meaning blame the physician for product misuse. In response, the manager responds that the issues cannot be linked to the IFU because the physician is well trained and experienced.¹⁵⁰

By early 2013, Ethicon began a design change for the TVT Exact.¹⁵¹ This included reviewing the IFU, testing the bending strength, and modifying the geometries of the trocar shaft tip and trocar sheath inner tip.¹⁵² In July 2013, Ethicon submitted a new Special 510k to clear a modified trocar design. The design changed the trocar from a “Chamfer tip” to a tapered tip, the geometry of the internal tip from flat to tapered, and an updated IFU reflecting the new look.¹⁵³

Importantly, at no time did Ethicon warn doctors about any issue regarding these issues or let them know that a modified TVT Exact was submitted to the FDA and would hopefully be available soon. In fact, Ethicon did just the opposite. On August 23, 2013, the FDA cleared the modified TVT Exact. Scott Jones, a marketing employee, emailed an update telling sales reps that

¹⁴⁵ ETH.MESH.12881753 at 1758-69.

¹⁴⁶ *Id.*

¹⁴⁷ ETH.MESH.08578490 at 8492.

¹⁴⁸ ETH.MESH.08578490 at 8491.

¹⁴⁹ ETH.MESH.08582600.

¹⁵⁰ ETH.MESH.08578490.

¹⁵¹ ETH.MESH.12839381.

¹⁵² *Id.*; ETH.MESH.12868401.

¹⁵³ ETH.MESH.12868401 at 8430.

“no action is required for existing product that has been manufactured prior to the modification” and that all remaining TVT Exact can still be used.¹⁵⁴ Thus, Ethicon did not tell doctors about the risk of continuing to use the old product.

It is my opinion that the blunted tips resulted in additional tissue and nerve trauma leading to chronic pain and dyspareunia which can be shown through the additional force required to pass the blunted trocar and sheath through resulting in bending, breaking, and cracking of the trocar and sheath when implanting the device. This is also something that would have been seen in gathering clinical data prior to the launch of the product. Additionally, Ethicon should have warned physicians about this increased risk or instructed them on how to modify the procedure. Without such knowledge, physicians were improperly warned and could not communicate the increased risks to the patient.

F. POST-MARKETING ADVERSE EVENTS

Ethicon did not actively try to determine how many patients were hurt by its devices, including the TVT Exact, or how severely they were hurt. Instead, Ethicon had a “passive” system of measuring how many and what type of adverse events the TVT Exact was causing. Ethicon’s Director of Post-Marketing Surveillance testified that this type of passive collecting of reports understates how many people are actually being hurt by its devices:

THE WITNESS: So we -- from a reactive perspective for complaints, we can only process the complaints that are reported to us, so -- and as we discussed earlier, they come from many different avenues; but again, they're reactive in nature, which means we are processing what is given to us or reported to us.

...

Q. You understand that spontaneous adverse event reporting, such as your department collects and analyzes, has been demonstrated to substantially under quantify the real complications in the world?

¹⁵⁴ ETH.MESH.12844215

- A. So the adverse events that are reported to us, complications, complaints that are reported to us, are a subset of the events, complaints, complications that occur in the field.¹⁵⁵

In fact, Ethicon employees ensured that they would not “actively” collect any complaints. When discussing how to perform a marketing survey with a number of physicians, Dan Smith wanted to ensure Ethicon people did not ask physicians questions that might “collect” a complaint:

Just a thought with regard to us collecting information. Paul, what was the ruling from our compliance group regarding us asking questions/collecting data, did we have to log issues as complaints???? et cetera. If so, we should do this in a manner that avoids this issue.¹⁵⁶

Dr. David Robinson, Ethicon’s Medical Director, noted a reason that Ethicon might not want to actively collect adverse events about its products: “[I]f this starts getting reported, it is going to scare the daylights out of docs.”¹⁵⁷

Even though Ethicon limited its “surveillance” to passively collecting complaints, it did not do this well. For example, Mark Yale, the head of Ethicon’s Worldwide Customer Quality team testified that all Ethicon employees had a legal duty to report any and all complaints to the Company about which they became aware.¹⁵⁸ When shown documentation, Yale admitted that this collection system was flawed. For example, employees in a US call center failed to report complaints,¹⁵⁹ employees in Eastern Europe did not know they were required to inform the

¹⁵⁵ Lamont Dep. (4/4/13) 389:25-390:23; Yale Dep. (8/7/13) 126:20-127:7 (“So you would agree that generally in a passive complaint collection, which is what Ethicon had prior to this discussion about the registry, for example, in a passive collection, that it is well known and well recognized that adverse events are underreported. Correct? THE WITNESS: In general, the basic understanding in the world of complaints and adverse events is that you do not get 100 percent reporting, that, you know, it is not the perfect collection model to gather. So, yes, they are, in some manner, underreported.”).

¹⁵⁶ ETH.MESH.01811770.

¹⁵⁷ ETH.MESH.00756984 (Email from David Robinson, M.D. to Giselle Bonet and Marty Weisberg).

¹⁵⁸ Yale Dep. (8-7-2013) 140:12 to 140:16.

¹⁵⁹ Yale Dep. (8-7-2013) 145:12 to 145:15.

Company of complaints and adverse events,¹⁶⁰ one Portuguese employee testified that he would not have reported the complaint, but someone had already informed the regulatory authorities:

- Q. So Francisco in Portugal working for Johnson & Johnson Medical says he wouldn't have reported this to you, this complication, except for the fact that somebody reported it to their regulatory authorities. Right?
- A. That's what he wrote. Correct.¹⁶¹

This line of questioning led to a consistent theme about adverse events and complications tracking at Ethicon – you don't know what you don't know. Yale testified:

- Q. So as you sit here today, you have no idea how many other complaints didn't make it here from Portugal, because Francisco Noronha from Johnson & Johnson decided that if it wasn't reported to his regulatory agency, he's not going to tell you about it. Right?

THE WITNESS: I don't know what I don't know.¹⁶²

When David Menneret, an employee of the mesh manufacturer at Ethicon SARL received a complaint about mesh being frayed (a significant issue as discussed above) he was unsure whether to report it as a “complaint” into the Ethicon complaint tracking system. He wrote:

Please see attached below a letter...regarding Mesh fraying. I don't know exactly who should be informed of this kind of customer feeling so feel free to forward to anyone concerned. Do you think this should be entered as a complaint in the system?¹⁶³

Again, Yale testified that he could not know how many complaints went to the manufacturer about the fraying from the manufacturing process that ultimately were not reported to Ethicon's complaint tracking system. He testified as follows:

- Q. You don't know how many times Menneret didn't report a complaint either. Right? You don't know what you don't know. Right?

THE WITNESS: As I said before, I do not know what I do not know....¹⁶⁴

¹⁶⁰ Yale Dep. (8-7-2013) 155:21 to 155:25.

¹⁶¹ Yale Dep. (8-7-2013) 159:5 to 159:10.

¹⁶² Yale Dep. (8-7-2013) 160:16 to 160:24.

¹⁶³ ETH.MESH.01814252.

¹⁶⁴ Yale Dep. (8-7-2013) 168:24 to 169:12.

Prior to March of 2006, Ethicon did not even have a formal procedure in place to capture adverse events from its own clinical trials. Therefore, it had no idea how many adverse events occurred but were not reported from those trials.¹⁶⁵ Most importantly, Ethicon does not track the complaints for any trends in adverse events between laser cut mesh and mechanical cut mesh.¹⁶⁶ Katrin Elbert testified that “it would be very difficult to do, given the way complaint data comes in.”¹⁶⁷

In addition to the marketing materials, Ethicon also provided physicians with “Complications Statements” during training or upon request. These “Complication Statements” relied upon the information captured in Ethicon’s complaint system – the same system described above. Accordingly, the capture of information for these statements was already severely compromised. However, even for those events Ethicon did capture, the reporting of these events in the Complications Statements was completely misleading.

Joseph Scavona, a complaint analyst, was responsible for creating one of these Complications Statements that was provided to physicians. He described how he created the statement and how, if a woman had multiple injuries, he only listed one injury on the chart. He wrote:

[S]ome complaints could be described with multiple main & sub categories, but each complaint was only labeled with one of these categories (e.g. patient had pain, bleeding, hematoma, exposure, and dyspareunia thus complaint was coded only “mesh exposure”).¹⁶⁸

¹⁶⁵ Yale Dep. (8-7-2013) 194:22 to 195:7.

¹⁶⁶ Trial Transcript of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3438:3-3439:2; Trial Transcript of Piet Hinoul, *Batiste v. Ethicon and Johnson & Johnson, Inc.*, (3/27/2014) 40-45.

¹⁶⁷ Trial Transcript of Katrin Elbert, *Perry v. Luu, et al.* (2/11/15); 3438:14-19.

¹⁶⁸ ETH.MESH.02122904 (Ex. 970) (Email from Joseph Scavona to others re “TVT Complications Statement 2008”). Complications Statement attached at ETH.MESH.00007091 at 2 (Ex. T-970).

This completely misrepresented the actual harms data. Moreover, the person making these decision, Scavona, was not a medical doctor. He recognized these limitations and requested that medical review the complications data, but it did not occur.¹⁶⁹ Instead, physicians were provided with misleading, inaccurate and incomplete information in the Complications Statements.¹⁷⁰

In my opinion Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading. As manufacturers are the only entities with access to complaint information, physicians and patients must rely upon them to provide timely, accurate and complete information. Ethicon failed to do so. Without accurate information, physicians could not and cannot obtain informed consent from their patients, nor can patients give informed consent. Ethicon's complaint collecting and reporting system made this impossible.

G. ETHICON'S FAILURE TO DISCLOSE THE CONTENTS OF THE MSDS

According to Ethicon Medical Director, Dr. Martin Weisberg, a Material Safety Data Sheet (MSDS) is "a document that discusses the product, the composition, any potential hazards from it . . . Generally, the safety particular of products."¹⁷¹ As it relates to polypropylene, I have reviewed several MSDSs for polypropylene resin used to manufacturer meshes used in various pelvic floor meshes. All of the MSDSs discussed below are available to the public.

Sunoco, the manufacturer for the polypropylene resin used to manufacture Ethicon's pelvic floor products lists the possibility that polypropylene mesh can cause tumors or cancer. This is documented by the Sunoco MSDS¹⁷² from April 13, 2005 which states in relevant part:

OTHER INFORMATION

¹⁶⁹ *Id.*

¹⁷⁰ Yale Dep. (8-8-2013) 294 to 300.

¹⁷¹ Weisberg Dep. (8/9/13) 909:2-9.

¹⁷² ETH.MESH.02026591 at 6591-6595.

Follow all MSDS/label precautions even after container is emptied because it may retain product residue.

COMPONENT TOXICITY: Polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the implantation site. No epidemiological studies or case report suggest any chronic health hazard from long term exposure of polypropylene decomposition products below the irritation level. (OARC, 19, 128).¹⁷³

Dr. Martin Weisberg, Ethicon Medical Director, is not only familiar with this MSDS, he also has personal experience with it. Dr. Weisberg agrees that the manufacturer of Ethicon's mesh did a study by implanting it under the skin of rats and it did in fact induce sarcomas.¹⁷⁴ Dr. Weisberg also agrees "if there was evidence of cancer-causing abilities of polypropylene . . . a reasonable doctor would want to know."¹⁷⁵ And, despite evidence to the contrary in the above MSDS for the resin used to make the polypropylene mesh for TVT, he is not aware of any instance when Ethicon "disclosed to any doctor that there's any evidence that the use of polypropylene mesh might induce sarcomas in its patients."¹⁷⁶

Dr. David Robinson, a former Ethicon Medical Director, testified he was unaware of Ethicon ever performing any studies or research to determine whether polypropylene could cause cancer in the long term.¹⁷⁷ In addition, he testified that Ethicon never disclosed "the potential that polypropylene in the product could be cancer causing."¹⁷⁸ Dr. Robinson also testified that it would be reasonable for physicians to want to know about polypropylene possibly causing cancer.¹⁷⁹

Another MSDS from Chevron Phillips¹⁸⁰, a manufacturer of polypropylene resin states:

MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent

¹⁷³ *Id.* at 02026595.

¹⁷⁴ Weisberg Dep. (8/9/13) 951:6-10.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 951:11-16.

¹⁷⁷ Robinson Dep. (9/11/13) 1105:17-110:14.

¹⁷⁸ Robinson Dep. (9/11/13) 1114:15-18.

¹⁷⁹ Robinson Dep. (9/11/13), 1115:5-19.

¹⁸⁰ Chevron Materials Safety Data Sheet Marlex Polypropylenes (All Grades) Revision Number: 3 (Ex. T-3137).

implantation in the human body or permanent contact with internal body fluids or tissues.

Do not use this Chevron Phillips Chemical Company LP material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Chevron Phillips Chemical Company LP under an agreement which expressly acknowledges the contemplated use.

Chevron Phillips Chemical Company LP makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with the internal body fluids or tissues.

With respect to the Chevron Phillips MSDS, Ethicon Medical Director, Dr. Martin Weisberg, testified that he did not have the Chevron Phillips MSDS in 2001 when he reviewed the Sunoco MSDS and no one at Ethicon alerted him to it.¹⁸¹ If he had been alerted to the Chevron Phillips MSDS, it may have “triggered” an investigation on his part.¹⁸² He also believes that if Ethicon knew about this MSDS, Ethicon should have studied the issue and, if they did not do so, it would have been a violation of the company Credo.¹⁸³

Total Petrochemicals, the polypropylene resin manufacturer for the polypropylene used in AMS’ pelvic floor products, Technical Data Sheet for Polypropylene PPR 7220, states in bold red lettering “Under no circumstances are any products sold by Total Petrochemicals suitable for human or animal implants.” It is further documented that, “The above-mentioned product is NOT in compliance with the US pharmacopoeia because we DID NOT perform required tests.” (emphasis from the original document).¹⁸⁴

¹⁸¹ Weisberg Dep. (8/9/13) 944:16-945:5.

¹⁸² *Id.*

¹⁸³ *Id.* at 947:4-19.

¹⁸⁴ ETH.MESH.02026591.

The manufacturer of the polypropylene resin for the polypropylene used in competitor pelvic floor products, Phillips Sumika Polypropylene Company, included a similar warning in its MSDS.¹⁸⁵ Specifically, it states:

Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues. Do not use Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use. Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for the use in implantation in the human body or contact with internal body fluids or tissues.

As discussed above, the possibility that polypropylene mesh can cause tumors or cancer is documented in the Sunoco MSDS, the manufacturer of the polypropylene resin used in the TVT Prolene mesh.¹⁸⁶ Specifically, the Sunoco MSDS from April 13, 2005 states: COMPONENT TOXICITY: Polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the implantation site. No epidemiological studies or case report suggest any chronic health hazard from long term exposure of polypropylene decomposition products below the irritation level.”¹⁸⁷

Despite this warning in the MSDS for the polypropylene resin used to manufacture the TVT mesh, there is no evidence that Ethicon informed surgeon about this important information contained in various Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene. This information includes the dangers of using polypropylene in a permanent implanted medical

¹⁸⁵ Phillips Sumika Polypropylene Company Material Safety Data Sheet Marlex Polypropylene (All Grades) Revision Number: 5.03 Revision Date: 12/4/2008.

¹⁸⁶ ETH.MESH.02026591-6595.

¹⁸⁷ ETH.MESH.02026595.

device set forth in MSDS that were in the public domain and available to Ethicon if they chose to look. Ethicon also failed to inform physicians that laboratory studies on rats showed that polypropylene caused sarcomas.

The fact that this information has not been disclosed to physicians in any manner (IFUs, direct letters or promotional materials) is especially concerning in light of literature showing reports of cancer associated with polypropylene. Specifically, there have been cases of pseudotumor reported in polypropylene for hernia mesh¹⁸⁸ and inflammatory myofibroblastic tumor of low malignant potential with a TVT device.¹⁸⁹ In addition, there have been 2 cases of bowel cancer associated with mesh used for abdominal sacrocolpopexy, one associated with mersilene and one with polypropylene and TVT placement.¹⁹⁰ A case of primary vaginal leiomyosarcoma associated with TVT and anterior repair with Bard Duraderm has also been reported.¹⁹¹

Finally, a report of angiosarcoma associated with Darcon vascular grafts was reported in 1999.¹⁹² The authors of this article noted at least 8 other sarcomas developing at the site of vascular prosthesis, and that the rate of these sarcoma, associated with foreign bodies, was much higher than the rate of sarcomas in general. All sarcomas associated with Darcon grafts were high grade histology and disseminated at the time of presentation. The authors also describe sarcoma reported at the site of other foreign bodies, such as shrapnel, bullets, steel plates and retained surgical sponges. They also note that the latency period from the acquisition of the foreign body and the development of sarcoma had a mean of 33 years. They document that a chronic foreign body

¹⁸⁸ Karrem, M., Community Oncology, Volume 7/Number 4/April 2010.

¹⁸⁹ Kwon S., et al, Female Pelvic Med Reconstruct Surg, Volume 18, Number 4, July/August 2012.

¹⁹⁰ Ahuja, S., et al, Gynecol Surg 2011, 8:217-221.

¹⁹¹ Moller, K., et al, Gynecologic Oncology 94 (2004) 840-842.

¹⁹² Ben-Izhak, O., et al, Am J Surg Pathology, Issue: Volume 23 (11), 1999, p. 1418.

reaction, the same "microscopic foreign body reaction" described by Dr. David Robinson in his Sept 2013 deposition as being clinically insignificant, was the etiology of this carcinogenesis. The authors also describe sarcomas developing in rodents after inert plastic polymers were placed in their soft tissue: "The sarcomas developed in rodents in which thick fibrous capsules developed around the implanted material." The authors conclude: "For unknown reasons, the cells in this inflammatory and repair process may undergo a malignant transformation, probably associated with oncogene activation and tumor suppressor gene inactivation. Further studies are warranted to search for the mechanisms involved in foreign body tumorigenesis." To date no manufacturer of mesh products has investigated this oncogenic potential as the authors recommended. In a report from the International Agency for Research on Cancer: Surgical Implants and Other Foreign Bodies, "When several polymers were tested in rats according to the same experimental protocol, sarcoma incidences ranged from 70% (polypropylene) to 7% (silicone)."¹⁹³ "Polymeric implants prepared as thin smooth films (with the exception of poly(glycolic acid)) are POSSIBLY CARCINOGENIC TO HUMANS."¹⁹⁴

Given the fact that hernia mesh placement increased in the 1990's with the advent of laparoscopic placement, and that vaginal mesh placed for SUI and POP accelerated in the 2000's, we may be on the cusp of an ever increasing number of foreign body tumors associated with vaginal mesh. Ethicon did not undertake any long term testing to determine whether or not these warnings on the polypropylene resin manufacturers MSDS were associated with long term consequences for permanent human use. This is true despite the fact that Ethicon has knowledge

¹⁹³ International Agency for Research on Cancer, Summaries and Evaluations, Vol.:74 (1999).

¹⁹⁴ McGregor, D.B., et al, European Journal of Cancer 36 (2000) 307-313 (emphasis added).

of three of these cancer reports (Kwon, Moller and Ahuja) as they are referenced in Ethicon's 2013 Clinical Evaluation Report regarding TVT.¹⁹⁵

Additionally, there is no evidence that Ethicon made any effort to inform surgeons of important information contained in various Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene. This information includes the dangers of using polypropylene in a permanent implanted medical device. And, that laboratory studies on rats showed that polypropylene caused sarcomas in laboratory rats. Clearly, these facts are critical information relevant to both the surgeon evaluating his or her treatment options and to the patient's informed consent decisions. As a result, Ethicon failed to act like a reasonable and prudent medical device manufacturer.

H. POLYPROPYLENE MESH IS CYTOTOXIC.

Cytotoxicity means toxicity to the cells causing cell injury or death.¹⁹⁶ In a May 26, 2000, Ethicon Memo titled "Review of biocompatibility on the tension-free vaginal tape (TVT) system for compliance to FDA,"¹⁹⁷ the review contains a "Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device" from August 8, 1997.¹⁹⁸ The Cytotoxicity Assessment states "there is some evidence to suggest that the PP [polypropylene] mesh from the sterile Ulmsten device maybe have cytotoxic potential.¹⁹⁹ In addition, ISO Elution testing, resulted in marked cytotoxicity in tests conducted at Ethicon (Scotland)."

According to former Ethicon Medical Director, Dr. David Robinson, Ethicon never performed "a single long-term study. . . to determine whether or not the Ethicon mesh clinically

¹⁹⁵ ETH.MESH.10150515.

¹⁹⁶ McGregor, D.B., et al, European Journal of Cancer 36 (2000) 307-313 (emphasis added).

¹⁹⁷ ETH.MESH.06852118 at 2118-2119 (5/26/2000 Biocompatibility Review).

¹⁹⁸ ETH.MESH.06852120 (8/8/1997 Cytotoxicity Risk Assessment).

¹⁹⁹ *Id.* and Robinson Dep. (9/11/13) 1098:23-1099:9.

cytotoxic in women.”²⁰⁰ In addition, in its IFU and Patient Brochures, Ethicon never informed physicians or their patients about the possibility of cytotoxicity.²⁰¹ Dr. Robinson testified that if there is a clinical related outcome related to cytotoxicity, it is reasonable for physicians to want to know that the mesh in the TVT product had been tested multiple times to be severely or marked cytotoxic.²⁰²

Cytotoxicity can cause death to cells that can lead to an inflammatory response leading to a multitude of injuries, including serious adverse complications such as erosions, chronic pelvic pain, recurrence, worsening incontinence, dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction or the need for additional surgeries. Ethicon did not undertake any long term testing to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use. This is true despite the fact that its own test results showed the mesh to be cytotoxic.

The potential for cytotoxicity or cell death is important information the physicians need to know in order to pass the information on to their patients so that an informed decision can be made about whether to have a permanent medical device implanted in their body. It is clear from Ethicon’s Medical Director, Dr. David Robinson, that this information was never passed on to physicians despite the fact that it would have been reasonable for physicians to have this information. As a result, Ethicon did not act as a reasonably prudent medical device manufacturer in that it failed to inform physicians and their patients about the risk of its mesh being cytotoxic.

²⁰⁰ Robinson Dep. (9/11/13) 1101:24-1102:5.

²⁰¹ Robinson Dep. (9/11/13) 1114:15-18.

²⁰² Robinson Dep. (9/11/13) 1115:5-19.

I. THE BENEFITS OF TVT EXACT ARE OUTWEIGHED BY ITS COMPLICATIONS.

It is my opinion, based on my training, experience and extensive review of the literature and Ethicon's internal documents that the benefits of the TVT Exact are outweighed by the severe, debilitating and life changing complications associated with the medical device. It is clear that a substantial number of women who are implanted with the TVT Exact have already and will continue to suffer chronic, debilitating erosions or pain, among other complications, and these life changing complications outweigh the benefits of the TVT Exact, a device used to treat a quality of life issue.

This is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications. The efficacy of the TVT Exact is equivalent to the traditional surgeries like the Burch. Traditional surgeries are not associated with TVT Exact mesh based complications like contraction and erosion, however, with clinically significant erosion. And, further, although traditional surgeries can cause symptoms such as pain following surgery, including dyspareunia, the risk, duration, extent and severity of chronic pain including dyspareunia following the TVT Exact is much greater than with traditional surgeries, and of course those surgeries do not result in the often untreatable complications and symptoms that result from the TVT Exact mesh.

There were reasonably feasible alternatives available to Ethicon for the treatment of patients in this case. For example, the Burch procedure would have been an appropriate treatment for SUI. The Burch procedure eliminates the risks specifically associated with the old construction heavyweight mesh used in the TVT Exact because the Burch procedure does not require the use of mesh. Another feasible alternative to the TVT Exact would have included autologous fascia

slings that also do not require the use of mesh. Additionally, based on Ethicon's internal document, deposition testimony, and medical literature, feasible alternatives would have included individually or collectively lighter weight, larger pore mesh material. Ethicon had lighter weight, larger pore meshes that were less stiff and more compliant with patients' tissues that it marketed for use in the pelvis.

The lack of any TVT Exact clinical data is especially problematic. This void in studying and presenting the true incidence and nature of long term and life altering complications, along with the biases inherent in many of the relied upon studies, and other factors, negates their value, and as a result, other sources of data such as published case series are relevant and important to truly understand the nature of these complications. Ethicon's internal documents and data, which are not publically available, present a very different picture of the TVT Exact than the information that has been shared with patients and physicians.

V. CONCLUSION

Ethicon has marketed and sold the TVT Exact despite the fact that it contains numerous characteristics that make it unsuitable for implantation in a woman's vagina. These characteristics include the following: (1) excessive rigidity; (2) degradation of the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh.

Not only does Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and benefits of the TVT Exact and made it impossible for women to consent to the procedure. In addition, despite having

knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT Exact was associated with cancer and could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures, the TVT Exact has caused and will continue to cause a multitude of injuries in women, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

All opinions I have are to a reasonable degree of medical certainty. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions and expert reports of both Plaintiff and Defense experts.

Signed this 17th day of January, 2016.

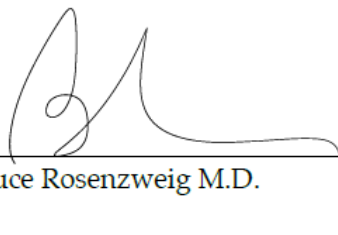
X 
Bruce Rosenzweig M.D.

EXHIBIT A

Bruce A. Rosenzweig, MD

CURRICULUM VITAE

NAME: Bruce A. Rosenzweig, M.D.

ADDRESS: 175 East Delaware Suite 8909
Chicago, Illinois 60611

DATE OF BIRTH: November 16, 1957

PLACE OF BIRTH: New York City, New York

MARITAL STATUS: Married

EDUCATION: Fellowship

1989 - 1991 Urologic Gynecology and Urodynamics
Harbor/UCLA Medical Center
Department of Obstetrics and Gynecology
Torrance, California

1988 - 1989 Pelvic Surgery
State University of New York
Department of Obstetrics and Gynecology
Syracuse, New York

Residency

1984 - 1988 Obstetrics and Gynecology
Michael Reese Hospital and Medical Center
Department of Obstetrics and Gynecology
Chicago, Illinois

1987 - 1988 Administrative Chief Resident

Graduate

1980 - 1984 University of Michigan Medical School
Ann Arbor, Michigan

1980 - 1984 Academic Tuition Scholarship
University of Michigan Medical School

Undergraduate

1976 - 1980 University of Michigan
Ann Arbor, Michigan - BS in Zoology
1976 University of Michigan Alumni Scholarship,
Illinois Chapter
1976 Bronsted Freshman Prize

Bruce A. Rosenzweig, MD

POSITIONS/APPOINTMENTS:

2011- 2012	Associate Chair Weiss Memorial Hospital Department of Gynecology Chicago, Illinois
2003- 2010	Attending Physician John H. Stroger Jr. Hospital Department of Obstetrics and Gynecology Chicago, Illinois
2002 - Present	Attending Physician Department of Obstetrics and Gynecology Rush Presbyterian St. Luke Hospital Chicago, Illinois
2002 - Present	Assistant Professor Rush Medical College Chicago, Illinois
1997 - 2005	Attending Physician Department Obstetrics and Gynecology Mercy Hospital and Medical Center Head Urogynecology Chicago, Illinois
1995 - 1998	Attending Physician Department of Women's Health Department of Veterans Affairs Westside Veterans Hospital Chicago, Illinois
1994 - 1998	Associate Professor Department of Obstetrics and Gynecology and Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1992 - 1994	Assistant Professor Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Associate Residency Program Director Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Head of Gynecologic Urology Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Attending Physician Department of Obstetrics and Gynecology Michael Reese Hospital and Medical Center Chicago, Illinois

Bruce A. Rosenzweig, MD

POSITIONS/APPOINTMENTS (Cont):

1991 - 1994	Assistant Professor Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1990 - 1991	Clinical Instructor Department of Obstetrics and Gynecology UCLA School of Medicine Los Angeles, California
1989 - 1991	Attending Physician Department of Obstetrics and Gynecology Harbor/UCLA Medical Center Torrance, California
1988 - 1989	Clinical Instructor Department of Obstetrics and Gynecology State University of New York Health Science Center Syracuse, New York
1988 - 1989	Attending Physician Department of Obstetrics and Gynecology Crouse-Irving Memorial Hospital Syracuse, New York

PROFESSIONAL SPORTS TEAM PHYSICIAN

2011- Present	Chicago Sky Women's Basketball Team
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LICENSURE:

1984	State of Illinois, #036-071719
1988	State of New York, #175147 (inactive)
1989	State of California, #G065470 (inactive)
1985	State of Illinois Controlled Substance, #003-136655
1985	DEA #BR0291815

SPECIALTY BOARDS:

1985	Diplomate of National Board of Medical Examiner
1991	Diplomate of American Board of Obstetrics and Gynecology (Recertified 2005)

JOURNAL EDITORIAL BOARD:

JOURNAL OF GYNECOLOGIC SURGERY
JOURNAL REVIEWER AND CONSULTANT

OBSTETRICS AND GYNECOLOGY

JOURNAL OF GYNECOLOGIC SURGERY

SURGERY GYNECOLOGY AND OBSTETRICS
ABSTRACTOR: International Abstracts of Surgery;

INTERNATIONAL UROGYNECOLOGY JOURNAL

Bruce A. Rosenzweig, MD

JOURNAL EDITORIAL BOARD (Cont):

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION
CONSULTANT: Diagnostic and Therapeutic Technology
Assessment (DATTA),

AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY

PSYCHOSOMATIC MEDICINE

SOUTHERN MEDICAL JOURNAL

JOURNAL OF HOSPITAL MEDICINE

INTERNATIONAL JOURNAL OF OBSTETRICS AND GYNECOLOGY

TEACHING AWARDS:

1997	CREOG National Faculty Resident Teaching Award
1993	APGO Excellence in Undergraduate Medical Education Award

MEDICAL ADVISORY BOARDS:

1993 - 1995	EMPI, Inc. St. Paul, Minnesota
1997 - 1999	EmpowerMed Yardley, Pennsylvania
2001 - 2003	Medcases Philadelphia, Pennsylvania

MEMBERSHIP ACTIVITIES AND COMMITTEES:**Michael Reese Hospital and Medical Center**

1987 - 1988	Chief Resident's Council
1987 - 1988	Residency Evaluation Committee
1988	Hospital Utilization Review Committee

Harbor-UCLA Medical Center

1989 - 1991	Surgical Case Review Committee.
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University of Illinois at Chicago, College of Medicine

1991 - 1993	Committee on Hospital Infections
1991 - 1997	OB/GYN Department Quality Assurance Committee
1991 - 1993	Medical Staff Quality Assurance Committee
1993	Ad Hoc Pap Smear Task Force
1993	Ad Hoc Committee to Review the 5 Year Deceleration Medical Student Program
1995 - 1997	Medical Records Committee
1996 - 1997	Generalist Curriculum Subcommittee
1997	Committee to Review the Performance of the Head of the Department of Urology

Bruce A. Rosenzweig, MD

GRANTS AND CONTRACTS:

1989 - 1990	#PQ 1402-02B Investigator "A Randomized, Controlled, Comparative Clinical Trial of Thiamphenicol Glycinate/Thiamphenicol Versus Cefoxitin/Doxycycline in the Treatment of Pelvic Inflammatory Disease." Sponsor: <i>Pharmaquest Corporation</i>
1989 - 1991	#35614-87 Investigator "A Randomized, Open-Label, Comparative, Multicenter, Safety, Tolerance and Efficacy Study of Parenteral Piperacillin/Tazobactam (CL 298.741) versus Clindamycin Plus Gentamicin in the Treatment of Hospitalized Patients with Gynecologic Infections." Sponsor: <i>American Cyanamid</i>
1990 - 1991	#MDS 401-US Investigator "Micturin versus Placebo in the Treatment of Urge Incontinence in Females. " Sponsor: <i>Forest Laboratories</i>
1992 - 1993	#C91-002 Principal Investigator "A Six Month Evaluation of Efficacy, Safety and Tolerance of the Lea's Shield. A Vaginal Barrier Contraceptive Device." Sponsor: <i>Contraceptive Research and Development Program</i>
1995 - 1997	#1393-027 Principal Investigator "Phase II Safety and Efficacy Study of Fem Cap Used With and Without Spermicide. " Sponsor: <i>Contraceptive Research and Development Program</i>

INVENTIONS AND PATENTS:

1. Double Lumen Amnioinfusion Catheter. U.S. Patent Number 4,722,730,
February 2, 1998. "Amcath". Manufactured by Gish Biomedical, Santa Ana, California.
2. "Meconium Aspirator Set." Manufactured by Gish Biomedical, Santa Ana, California.

VIDEO PRESENTATIONS:

Freedman A, Rosenzweig B, Maurice J., An Interesting Presentation of Failed Medical Termination with Hysteroscopic Resection of Retained Products of Conception. 41st Global Congress of minimally Invasive Gynecology Las Vegas, Nevada November 2012

MULTIMEDIA

FILM

1. *Design*. Feature Film. Premiere Sundance Film Festival January 2002. Co-Producer.
2. *Kwik-Stop*. Feature Film. Premiere Los Angeles Film Festival April 2001. Actor.
3. *The 95th*. Documentary. Premiere Maryland Film Festival May 2002. Co-Producer.
4. *Independent films and filmmakers*. Short Documentary. 1998. Producer, Director.

COMPUTER INTERACTIVE TEACHING PROGRAMS

Urogynecology: Evaluation and Treatment of Urinary Incontinence. CD Rom; Produced
by Interactive Medical Review, Philadelphia, Pennsylvania, 1994.

MULTIMEDIA (Cont):

Bruce A. Rosenzweig, MD

STREAMING MEDIA

1. Live Webcast of the First Streaming Media Conference. 1998. Producer, Director.

INDUSTRIAL VIDEO

1. *A Day at the Office*. WellSpring Management Group, Bethany, Connecticut. 1998. Producer, Director.
2. *Point of View Skiing*. American Ski Corporation, Sugarbush, Vermont. 1998. Producer.
3. *Promotional Video*. IMET Coporation, Philadelphia, Pennsylvania. 1999. Producer, Director.

PRESENTATIONS AND INVITED LECTURES:

Michael Reese Hospital and Medical Center

1. "A Prospective Randomized Study Comparing Nipple Stimulation and Exogenous Oxytocin Contraction Stress Tests." Presented at the First Annual Resident Research Conference, Michael Reese Hospital and Medical Center, Chicago, Illinois. June 11, 1987.
2. "Postpartum Uterine Inversion." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. September 10, 1987.
3. Faculty Member: Basic and Advanced Laser Surgery, Hysteroscopy, Colposcopy, and Operative Laparoscopy, A "Hands-On" Course and Seminar, Washington, DC. January 25-28, 1989.
4. "Tubo-ovarian Abscess: Medical versus Surgical- Management." Grand Rounds, University of Nairobi, Nairobi, Kenya. March 2, 1989.
5. "HPV DNA and Squamous Atypia." Presented at the Tenth Annual Scientific Congress and Advanced Postgraduate Laser Course of the Gynecologic Laser Society, Orlando, Florida. March 31, 1989.
6. "Postpartum Uterine Inversion: Diagnosis and Management." Grand Rounds, SUNY-HSC, Syracuse, New York. March 17, 1989
7. Faculty Member: Basic and Advanced Laser Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Virginia Beach, Virginia. July 24-28, 1989.
8. "HPV: The Disease of the 80's." Presented at the Los Angeles Regional Family Planning Council Family Planning Symposium, Torrance, California. January 20, 1990.
9. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, and Pelviscopy, A "Hands-On" Course and Seminar, Washington, DC. January 24-27, 1990.
10. "Office of Evaluation of Urinary Incontinence." Luncheon Conference at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, San Francisco, California. May 8, 1990.
11. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, Pelviscopy. A complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 23-27, 1990.
12. "Lasers in Gynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Ancreles, California. September 27, 1990.
13. "Urinary Incontinence and Genital Prolapse." Grand Rounds, HarborUCLA Medical Center, Torrance, California. October 15, 1990.

Bruce A. Rosenzweig, MD

PRESENTATIONS AND INVITED LECTURES (Cont):

14. Course Director: Contraceptive Technology: Symposium on Managing the IUD Patient. Planned Parenthood of San Diego and Riverside Counties, San Diego, California. October 27, 1990.
15. "Lasers in Urogynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Angeles, California. November 8, 1990.
16. Course Director: Contraception in the 90's, Managing the IUD Patient. Oklahoma State Department of Health Maternal and Child Health Services, Oklahoma City, Oklahoma. March 1, 1991.
17. "Office Evaluation of Urinary Incontinence." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. April 4, 1991.
18. Urinary Incontinence and Genital Prolapse. " Grand Rounds, University of Illinois at Chicago, College of Medicine, Chicago, Illinois. April 8, 1991.
19. "Urinary Incontinence." Women's Healthcare Center, Torrance, California. April 25, 1991.
20. "Evaluation and Management of Urinary Incontinence." South Bay Perinatal Access Project, San Pedro, California. May 3, 1991.
21. "Office Evaluation of Incontinent Women." Luncheon Conference at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 7, 1991.
22. "Surgical Choices for Incontinence. " Luncheon Conference at the Thirty-Ninth Annual Meeting of American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 8, 1991.
23. AUGS Special Interest Session: "Gynecological Urology: Case Management in Urogynecology. At the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 8, 1991.
24. "Vulvar and Vaginal Diseases." Colposcopy Training Course, Torrance, California. May 30, 1991.
25. "Managing the IUD Patient." Grand Rounds, Glendale Adventist Hospital, Glendale, California. June 10, 1991.
26. Course Director: Managing the IUD Patient. Arizona Family Planning Council, Phoenix, Arizona. June 15, 1991.
27. "Basic Urogynecologic Instrumentation; Proper Evaluation and Differential Diagnosis of Stress Urinary Incontinence." Gynecologic and Endoscopic Surgery. A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 22, 1991.
28. "Evaluation and Management of Urinary Incontinence." At the Fourth Annual National Association of Womens' Health Professional Conference, Chicago, Illinois. October 17, 1991.
29. Course Coordinator: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology: A Hands-On Seminar. "Evaluation of the Incontinent Patient; IUD Update; Nonsurgical Management of the Incontinence." Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology, Snowbird, Utah. March 11-14, 1992.
30. "Managing the IUD Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. March 19, 1992.

Bruce A. Rosenzweig, MD

PRESENTATIONS AND INVITED LECTURES (Cont):

31. "Evaluation and Nonsurgical Management of the Incontinent Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. April 2 & 19, 1992.
32. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, and "Evaluation of the Incontinence Patient." Visiting Professor Lecture, Albert Einstein Hospital, Philadelphia, Pennsylvania. April 6, 1992.
33. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. April 7, 1992.
34. "Surgery in the Elderly. Female Urinary Incontinence: A Gynecologists Point of View." At the United States Section of the International College of Surgeons, Chicago, Illinois. April 10, 1992.
35. "Managing the IUD Patient." American College of -Nurse Midwives. Illinois Chapter Meeting. University of Illinois, College of Nursing, Chicago, Illinois. April 13, 1992.
36. "Contraceptive Choices in the 1990's." Postgraduate Course at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Las Vegas, Nevada. April 28-29, 1992.
37. "IUD and Contraception." Grand Rounds, Mount Sinai Hospital and Medical Center, Chicago, Illinois. May 6, 1992.
38. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Cook County Hospital, Chicago, Illinois. May 11, 1992.
39. "Managing the IUD Patient." Grand Rounds, Ravenswood Hospital, Chicago, Illinois. May 21, 1992.
40. "Nonsurgical Management of Urinary Incontinence. Grand Rounds, Humana Hospital/Michael Reese and Medical Center, Chicago, Illinois. June 4, 1992.
41. "Urinary Dysfunction." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 5, 1992.
42. "Surgical Management Stress Incontinence of Urine; Management of Operative Complications; Comparison of Techniques for Management of CIN. Advanced Gynecologic Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 20-22, 1992.
43. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Cook County Hospital, Chicago, Illinois. July 27, 1992.
44. "Nonsurgical Approach to Female Incontinence." Grand Rounds, Alexian Brothers Medical Center, Elk Grove Village, Illinois. September 3, 1992.
45. Course Director: Update on Urogynecology. "Evaluation of the Incontinent Patient; Nonsurgical Management of Stress Urinary Incontinence." Update on Urogynecology, Philadelphia, Pennsylvania. September 21, 1992.
46. "Urinary Incontinence: It Doesn't Have to be Part of a Woman's Everyday Life." Virginia Baptist Hospital, Lynchburg, Virginia. October 13, 1992.
47. "Managing the IUD Patient. Grand Rounds, Hershey Medical Center, Hershey, Pennsylvania. October 21, 1992.
48. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, University of Illinois at Champaign, Champaign, Illinois. October 28, 1992.

Bruce A. Rosenzweig, MD

PRESENTATIONS AND INVITED LECTURES (Cont):

49. "Evaluation and Management of Urologic Problems in Women. " Gynecological Update 1991, La Mesa, California. October 31, 1992.

50. "IUD Insertion/Removal and Model Practicum. At the Annual Family Planning, Obstetrics and Gynecology Update for Florida Nurse Practitioners, Orlando, Florida. November 5, 1992.

51. "IUD's Revisited." At the Statewide Clinician's Meeting, Planned Parenthood Wisconsin, Milwaukee, Wisconsin. November 13, 1992.

52. "The Nonsurgical Management of Stress Urinary Incontinence." Grand Rounds, University Hospital of Cleveland, Cleveland, Ohio. November 18, 1992.

53. "The IUD: A Second Look." A Contraceptive Symposium and Practicum. San Bernadino County Department of Public Health. Womens' Health Section, San Bernadino, California. November 20, 1992.

54. "Managing the IUD Patient." Grand Rounds, Department of Family Practice, University of Illinois, Chicago, Illinois. December 2, 1992.

55. "Managing the IUD Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. January 12, 1993.

56. "Repair of Pelvic Floor Dysfunction; Voiding Disorders and How to Manage Them." Advanced Gynecologic Surgery, Washington, D.C. January 27, 1993.

57. Course Director: Controversies in Gynecology. "Nonsurgical Management of Stress Urinary Incontinence; Genital Prolapse and Lower Urinary Tract Dysfunction Controversies in Gynecology, St. Petersburg, Florida. February 11-12, 1993.

58. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Saginaw General Hospital, Saginaw, Michigan. February 15, 1993.

59. "Managing the IUD Patient." Oklahoma State Department of Health Practitioners Annual Meeting, Oklahoma City, Oklahoma. March 11, 1993.

60. Course Director: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology. "Genital Prolapse and Lower Urinary Tract Dysfunction; Physiotherapy in the Treatment of Lower Urinary Tract Dysfunction; Surgical Management of Stress Urinary Incontinence; The Role of IUD's in Contraception." Beaver Creek Colorado. March 17-20, 1993.

61. "Managing the IUD Patient." Grand Rounds, Waukesha Memorial Hospital, Waukesha, Wisconsin. March 23, 1993.

62. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Evanston Hospital, Evanston, Illinois. March 25, 1993.

63. "Evaluation of the Incontinent Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. March 29, 1993.

64. "Managing the IUD Patient." Grand Rounds, Forbes Metro Hospital, Pittsburgh, Pennsylvania. March 30, 1993.

65. "Incontinence Differential Diagnosis, History and Physical Exam; Pelvic Floor Neurology for the Gynecologist: EMG and Pudendal Conduction Latency; Other Cause of Incontinence." At Urogynecology 1993 State of the Art, Frisco, Colorado. April 2-3, 1992.

Bruce A. Rosenzweig, MD

PRESENTATIONS AND INVITED LECTURES (Cont):

66. "Intrauterine Device: Insertion and Management." Sixteenth Annual Seminar in Womens' Health Care, Dallas, Texas. April 16, 1993.

67. "Contraceptive Choices for the 1990's and Beyond." The Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Washington, D.C. May 4-5, 1993.

68. "Managing the IUD Patient." Grand Rounds, La Grange Hospital, La Grange, Illinois. May 17, 1993.

69. "Evaluation and Management of Urinary Incontinence." Grand Rounds, Mount Sinai Hospital, Miami, Florida. May 25, 1993.

70. "Contraceptive Update." At the Tenth Annual Medical Update, Pittsburgh, Pennsylvania. June 2, 1993.

71. "Treatment of Urinary Incontinence." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 10, 1993.

72. "Open Urinary Stress Incontinence Procedures." St. Louis, Missouri. June 16, 1993.

73. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Baylor College of Medicine, Houston, Texas. June 30, 1993.

74. "Urodynamic Testing; Nonsurgical Management of Urinary Incontinence; Bladder Injury: How to Avoid, How to Manage." At Principles of Advanced Conventional and Endoscopic Surgery, Palm Beach, Florida. July 26, 1993.

75. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence." The Gynecologic Surgical Techniques, Chicago, Illinois. August 19, 1993.

76. "Pelvic Anatomy and Placement of Sutures for Paravaginal Repair and Correction of Stress Incontinence." Demonstrated Using Human Cadaver, Chicago, Illinois. August 20, 1993.

77. Course Director: Practical Urogynecology. "Behavioral Management of Incontinence; Painful Voiding Syndrome; Behavioral and Physical Therapy for Urinary Incontinence." Cleveland, Ohio. August 27-38, 1993.

78. "Evaluation of the Incontinent Patient." Resident Lecture, East Carolina University, Greenville, North Carolina. September 22, 1993.

79. "Non-Hormonal Contraception." Grand Rounds, East Carolina University, Greenville, North Carolina, September 22, 1993.

80. "Gynecologic Disorders; Pregnancy Changes and General Surgical Problems During Pregnancy." Specialty Review in Surgical Critical Care, Chicago, Illinois, October 4, 1993.

81. "Managing the IUD Patient." Grand Rounds, George Baptist Medical Center, Atlanta, Georgia, October 12, 1993.

82. "Managing the IUD Patient." Grand Rounds, Reading, Pennsylvania. October 19, 1993.

83. "IUD Update: Clinical and Demographics Issues." Grand Rounds, Ohio State University, Columbus, Ohio. November 4, 1993.

84. "Update on Amnioinfusion." Grand Rounds, St. Francis Hospital, Blue Island, Illinois. November 16, 1993.

85. "Management of Urinary Stress Incontinence." St. Michael's Hospital, Toronto, Ontario, Canada. December 6, 1993.

86. "IUD Update: Clinical and Demographic Issues." Grand Rounds, Jackson Memorial

Bruce A. Rosenzweig, MD

Hospital, Miami, Florida. January 12, 1994.

PRESENTATIONS AND INVITED LECTURES (Cont):

87. "Urogynecology: Differential Diagnosis and Evaluation of Female Incontinence; Surgical Therapies for Stress Incontinence; Diagnosis and Treatment of Detrusor Instability; Diagnosis and Surgical Therapies for Stress Incontinence, Gynecologist." At Frontiers in Gynecology,

Steamboat Springs, Colorado. January 25-26, 1994.

88. "Genital Prolapse and Lower Urinary Tract Dysfunction." At the Fifth Annual Midwest Clinical Conference, Chicago Medical Society, Chicago, Illinois. February 11, 1994.

89. "Bacterial Vaginosis." Grand Rounds, Chicago Osteopathic Hospital, Chicago, Illinois. February 17, 1994.

90. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 18, 1994.

91. "Female Urinary Incontinence: Anatomy Physiology, Definitions; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc.; Diagnosis and Treatment of Pelvic Floor Disorders; Cystourethroscopy: Instrumentation and Technique; Ureteral Catheterization - Indications, Risks, Benefits." At Modern Menopause and Urogynecology, San Francisco, California. March 11-13, 1994.

92. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Kaiser Bellflower, Bellflower, California. March 29, 1994.

93. "Female Urinary Incontinence: Anatomy, Physiology, Definitions; Office Evaluation and Advanced Urodynamic Testing; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc., Nonsurgical Therapies for Stress Incontinence; Cystourethroscopy: Instrumentation and Technique; Ureter Catheterization Indications, Risks, Benefits." At the Advanced Gynecologic Endoscopy with Urogynecology, Palm Springs, California. April 9-10, 1994.

94. "Intrauterine Device: Insertion and Management" at the 17th Annual Seminar in Womens' Health Care. Dallas, Texas. April 15, 1994.

95. "Surgical Management of Stress Urinary Incontinence." Grand Rounds, University of Illinois, Champaign, Illinois. April 15, 1994.

96. "Anatomy of Pelvic Floor Supporting System; Rational Anatomical Approach to Pelvic Floor Defects." At Advanced Laparoscopic Techniques, Chicago, Illinois. April 21, 1994.

97. "Managing the IUD Patient." Grand Rounds, University of Wisconsin, Milwaukee, Wisconsin. April 27, 1994.

98. "Contraceptive Choices." At the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. Orlando, Florida. May 10-11, 1994.

99. "Update on the IUD: New Friend or Old Danger." Grand Rounds, Harbor-UCLA Medical Center, Torrance, California. May 23, 1994.

100. "Contraception." At the Specialty Review in Obstetrics and Gynecology, Chicago, Illinois. May 24, 1994.

101. "Problem Management: IUD's. At the Twenty-Second Annual Conference for Nurse Practitioners in Reproductive Healthcare. Milwaukee, Wisconsin. June 10, 1994.

102. "Pelvic Floor Disorder." At the Obstetrics and Gynecology Review Course, Chicago, Illinois. June 15, 1994.

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PRESENTATIONS AND INVITED LECTURES (Cont):

103. "Female Urinary Incontinence: Treatment by Electrostimulation." Grand Rounds, Hospital du Sacre-Coeur, Montreal, Canada. June 16, 1994.

104. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Sparrow Hospital, Lansing, Michigan. June 21, 1994.

105. "Major Pelvic Hemorrhage: The Safest and Best Methods for Control; Vaginal Cones and Electrical Stimulation to Manage Stress Incontinence; What To Do With The Patient Who Continues To Leak After Multiple Incontinence Surgeries." At Operative Gynecology, Palm Beach, Florida. July 18-20, 1994.

106. "Repair of Genital Prolapse." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. August 17, 1994.

107. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence, Including Cystoscopy; Pelvic Anatomy and Placement of Sutures for Paravaginal Repair, Sacrospinous Fixation, and Connection of Stress Incontinence." At Gynecologic Surgical Techniques, Chicago, Illinois. August 18-19, 1994.

108. "Gynecologic Problems in Surgery; Surgery in Pregnant Women." At Specialty Review in General Surgery, Part I, Chicago, Illinois. August 22, 1994.

109. "Managing the IUD Patient." Grand Rounds, Medical College of Wisconsin, Milwaukee, Wisconsin. August 25, 1994.

110. "Managing the IUD Patient." Grand Rounds, Rush University, Chicago, Illinois. September 8, 1994.

111. "Gynecologic Problems in Surgery." At Specialty Review in General Surgery, Chicago, Illinois. September 19, 1994

112. "IUD Symposium." At the Colorado Department of Public Health, Womens' Health Symposium, Silverthorne, Colorado. October 5, 1994.

113. "Urinary Incontinence." Grand Rounds, St. Elizabeth Hospital, Chicago, Illinois. October 18, 1994.

114. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Christ Hospital, Oak Lawn, Illinois. October 24, 1994.

115. "Evaluation of Urinary Incontinence and the Bladder Neck Suspension." Atlanta, Georgia. November 18, 1994.

116. "Managing the IUD Patient." Grand Rounds, Mount Sinai Hospital, Hartford, Connecticut. January 6, 1995.

117. "Managing the IUD Patient." At the New Mexico Department of Health Clinicians Seminar, Albuquerque, New Mexico. January 26, 1995.

118. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 2, 1995.

119. "Urinary Incontinence in Women." At the Womens' Health Issues 1995, India Medical Association (IL), USA, Chicago, Illinois. March 12, 1995.

120. "Bacterial Vaginosis." Grand Rounds, Anchor HMO, Chicago, Illinois. March 28, 1995.

121. "Urinary Incontinence in Women: What's New." Metropolitan Chapter of the American

Bruce A. Rosenzweig, MD

College of Surgeons Meeting, Chicago, Illinois. April 27, 1995.

PRESENTATIONS AND INVITED LECTURES (Cont):

122. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." at the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, June 16-17, 1995.

123. "Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral syndrome, etc; Cystourethros copy - instrumentation and techniques; Urethral Catheterization indications, risk, benefits; abdominal procedures for GSI; non surgical therapy for GSI." at Advanced Gynecology Endoscopy and Uro-gynecology, Vancouver, Canada, August 19, 1995.

124. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." At the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, September 29-30, 1995.

125. "Managing the IUD Patient." At The Regional meeting of AMWA. Chicago, Illinois, September 23, 1995.

126. "The Evaluation of the Incontinent Patient and Bladder Neck Suspension." At the Operative Laparoscopy, Hysterectomy, Hysteroscopy and Pelvic Floor Repairs for gynecologists. Atlanta, Georgia, September 29-30, 1995.

127. "Manaaement of Severe Genital Prolapse. " Grand Rounds - University of Illinois Champaign, Illinois November 1, 1995.

128. "Pelvic Prolapse. " at the Obstetrics and Gynecology Tutorial - Oak Brook, Illinois, November 10, 1995.

129. "Algorithms for the Management Urinary Incontinence": A modern, systematic approach to Diagnosis and Treatment; Retropubic Operations for Stress Incontinence: Patient Selection, Techniques and Outcome; Cystovaginal and Rectovaginal Fistula Repair: Operations, Techniques and Outcomes. Operative Laparoscopy and Urogynecology Course, Steamboat Springs Colorado, February 7-9, 1996.

130. "Contraception" At the Osler Review Course, St. Louis, Missouri, April 21, 1996.

131. "Laparoscopic Bladder Neck Suspension; Vaginal Vault Suspension." at the Advanced Operative Endoscopy Course and Hysteroscopy Workshop, Palo Alto, California, June 1, 1996.

132. "Contraceptive Update" Osler Review Course, Chicago, Illinois, June 18, 1996.

133. "Menstrual Disorders; Urinary Incontinence; Pelvic Pain; Menopausal Syndrome. " Osler Review Course, Lisle, Illinois, July 10, 1996.

134. "Anatomy of the Pelvic Floor and Physiology of Incontinence; Evaluation of Urinary Incontinence and Pelvic Floor Disorders and Open Procedures for Urinary Incontinence. Cincinnati, Ohio, July 26, 1996.

135. "Role of Endoscopy in Reconstructive Pelvic Surgery; Evaluation of Urinary Incontinence and Open Surgical Management of Urinary Incontinence." At the Operative Gynecologic Hysteroscopy and Laparoscopy course Atlanta, Georgia, September 6-7, 1996

136. "An Overview of Urinary Stress Incontinence. " At the American Association of Gynecologic Laparoscopists, Chicago, Illinois, September 27, 1996.

137. "Gynecologic Problems in Surgery." General Surgery Review Course, Chicago, Illinois, October 9, 1996.

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138 "Contraception. " Chicago Area Review Course, Chicago, Illinois, October 16, 1996.

PRESENTATIONS AND INVITED LECTURES (Cont):

139. "Contraception. " Obstetrics and Gynecology Review, Chicago, Illinois, November 6, 1996.

140. "Contraceptive Update." Grand Rounds, Michael Reese Hospital, Chicago, Illinois, January 9, 1997.

141. "Contraceptive Update." Chicago Obstetrics and Gynecology Review, Chicago, Illinois, April 16, 1997.

142. "Contraception; Ectopic Pregnancy; Injections and Antibiotics; HIV and the Woman Patient; Obstetrical Emergencies." At the Obstetrics and Gynecology Review Course, St. Louis Missouri, April 23, 1997.

143. "Urinary Incontinence." "Practical Pearls for Women's Health Care: A Clinical Perspective" At the University of Illinois at Chicago, Illinois, May 17, 1997.

144. "Urinary Incontinence: Evaluation and Open Surgical Repair; Role of Laparoscopy in Pelvic Reconstructive Surgery." At the Laparoscopic Pelvic Surgery Course, Atlanta Georgia, May 23-24, 1997.

145. "Painful Bladder Syndromes." At the 25' Annual Conference for Nurse Practitioners in Women's Health, Milwaukee, Wisconsin, June 11, 1997.

146. "Contraception; Ectopic Pregnancy; Infections and Antibiotics." Arlington Heights, Illinois, June 25, 1997.

147. "Contraceptive Update." Springfield, Illinois, July 24, 1997.

148. "Evaluation and treatment of urinary incontinence; painful bladder syndromes: Interstitial cystitis, urethral syndrome, and sensory urgency; Treating pelvic floor dysfunction" at Advances in Health Care for Women Over 40. Jackson Hole, Wyoming, August 7-8, 1997.

PRESENTED ABSTRACTS:

1. Levy JS, Rosenzweig BA, Kaplan B, et al: Changed criteria for antenatal fetal heart rate testing: A five year single institution experience. Presented at the Eighth Annual Meeting of the Society of Perinatal Obstetricians, February 6, 1988, Las Vegas (Abstract #267).

2. Bergman F, Rotmensch S, Rosenzweig BA, et al: Analysis of Factor VIII complex and Von Willebrand factor multimers in preeclampsia. Presented at the Thirty-Sixth Annual Meeting of the Society for Gynecologic Investigation, March 17, 1989, San Diego (Abstract #277).

3. Thomas S, Karram M, Rosenzweig BA, Bhatia NN: Long-term experience with the Birch procedure: Effects of menopausal status on outcome. Presented at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, May 9, 1990, San Francisco.

4. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. Presented at the Twelfth Annual Symposium of the Urodynamics Society, May 12, 1990, New Orleans.

5. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in urology. Presented at the Eleventh Annual Meeting of the Gynecologic Laser Society, June 10, 1990, Chicago.

6. Rosenzweig BA, Bhatia NN, Hischke D, et al: The psychological profiles of women before and after surgical treatment of stress urinary incontinence. Proceeding of the Twentieth

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Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.

PRESENTED ABSTRACTS (Cont):

7. Rosenzweig BA, Bhatia NN: Temporal separation of urethral and bladder pressure spikes during cough in women with stress urinary incontinence, urge incontinence and after incontinence surgery. Proceeding of the Twentieth Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.
8. Rosenzweig BA, Bhatia NN, Hischke D, Thomas S, Nelson AL: The psychological status of women before and after treatment of stress incontinence. Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 1, 1990, Tarpon Springs.
9. Rosenzweig BA, Bhatia NN, Nelson AL: Pressure transmission ratio: What do the numbers really mean? Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 2, 1990, Tarpon Springs.
10. Rosenzweig BA, Blumenfeld D, Bhatia NN: Incidence of urinary incontinence in asymptomatic women with severe genitourinary prolapse: A rationale for preoperative urodynamic evaluation. Presented at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, May 7, 1991, New Orleans.
11. Rosenzweig BA, Blumenfeld D, Bhatia NN: Pessary test in the evaluation of detrusor instability in women with genitourinary prolapse. Proceeding of the Twenty-First Annual Meeting of the International Continence Society, October 10-12, 1991, Hannover, Germany.
12. Rosenzweig BA, Blumenfeld D, Bhatia NN: Detrusor instability in women with genitourinary prolapse: Correlation of pessary test with operative results. Presented at the Twelfth Annual Meeting of the American Uro-Gynecologic Society, October 23, 1991, Newport Beach
13. Rosenzweig BA, Bhatia NN, Karram. MM, Blumenfeld D: Management. of recurrent severe stress urinary incontinence using modified suburethral sling procedure: Autologous versus synthetic material. Presented at the Twelfth Annual Meeting of the American Uro Gynecologic Society, October 25, 1991, Newport Beach.
14. Rosenzweig BA, Prins GS, Bolina PS, et al: Steroid receptors of the lower urinary tract in the rabbit. Presented at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. May 5, 1993. Washington, DC.
15. Rosenzweig BA, Scotti RJ: The state of resident education in urogynecology. Presented at the CREOG and APGO Annual Meeting. March 2-5, 1994, Nashville.
16. Hopkins S, Rosenzweig B, Maurice J. Laparoscopic Retrieval of an Intraperitoneal Intrauterine Device. 42nd Global Conference of Minimally Invasive Gynecology. November 2013. Washington DC.

PUBLICATIONS:

BOOK CHAPTERS:

1. Gunning JE, Rosenzweig BA. Evolution of endoscopic surgery. In: White RA, Klein SR, eds. *Endoscopic Surgery*. St. Louis, Mosby-Yearbook, Inc., 1991:3.
2. Bhatia NN, Rosenzweig BA. The urologically oriented neurological examination. In: Ostergard DR, Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice*,

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3rd ed. Baltimore, Williams and Wilkins, 1991:102.

3. Rosenzweig BA. Endoscopy evaluation of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:124.

4. Rosenzweig BA. Radiologic studies of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:134.

BOOK CHAPTERS (Cont):

5. Lind LR, Rosenzweig BA, Bhatia NN. Urologically oriented neurological examination. In Ostergard Dr. Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice 4th ed.*, Baltimore, Williams and Wilkins, 1996:99.

6. Maurice JM, Rosenzweig BA. Acute Female Pelvic Pain *Common Surgical Diseases: An Algorithmic Approach, 3rd Edition*, In Press

LETTERS TO THE EDITOR:

1. Levy J, Rosenzweig BA, Blumenthal P: Amnioinfusion for fetal distress. *Am J Obstet Gynecol*, 1986;155:1361.

2. Levy J, Rosenzweig BA: Intubation and resuscitation of meconium-stained newborns. *Resp Care*, 1987;32:130.

3. Levy J, Rosenzweig BA, Blumenthal P: Comparison of uterine activity by nipple stimulation and oxytocin. *Obstet Gynecol*, 1987;70:430.

4. Blumenthal P, Rosenzweig BA: The prophylactic effect of doxycycline on postoperative infection rate after first-trimester abortion. *Obstet Gynecol*, 1988;72:146.

5. Rosenzweig BA: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? Letter (in reply). *Obstet Gynecol*, 1991;78:476.

PUBLISHED ABSTRACTS:

1. Rosenzweig BA, Rader JS, Padleckas R, et al: Correlation of human papillomavirus DNA and presence of atypical squamous cells in Pap smears. *Gynecol Oncol*, 1989;32:115.

2. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. *Neurourol Urodynam*, 1990;9:230.

ORIGINAL ARTICLES:

1. Rosenzweig BA, Rotmensch S, Ressetar A: Term interstitial pregnancy resulting in a live infant. *Obstet Gynecol*, 1988;72:491.

*2. Blumenthal PD, Rosenzweig BA, Levy JS, et al: Ectopic pregnancy prevalence at a tertiary urban obstetrical center: The roles of previous surgery, hospital self-selection and detection bias. *Am J Gynecol Health*, 1988;2:18.

3. Levy JS, Rosenzweig BA, Blumenthal L: Bilateral tubal pregnancies after tubal sterilization. *Obstet Gynecol*, 1988;72:494.

*4. Rosenzweig BA, Rotmensch S, Binette SP, Philippe M: Primary idiopathic polymyositis and dermatomyositis complicating pregnancy: Diagnosis and management. *Obstet Gynecol Surv*, 1989;34:950.

Bruce A. Rosenzweig, MD

5. Rosenzweig BA, Levy JS, Schipiour P, Blumenthal PD: Comparison of the nipple stimulation and exogenous oxytocin contraction stress tests: A randomized prospective study. *J Reprod Med*, 1989;34:950.

6. Rotmensch S, Rosenzweig BA, Philippe M: The impact of the AIDS epidemic on the philosophy of childbirth. *Am J Obstet Gynecol*, 1989; 161:855.

*** Non peer review**

ORIGINAL ARTICLES (Cont):

7. Rosenzweig BA, Seifer DB, Grand WD, et al: Urologic~ injury during vaginal hysterectomy. A case-control study. *J Gynecol Surg*, 1990;6:27.

*8. Rosenzweig BA, Birenbaum DL, Baggish MS: Pelvic inflammatory disease as a complication of carbon dioxide laser surgery of the cervix. *J Gynecol Surg*, 1989;5:117.

9. Baggish MS, Sze EHM, Rosenzweig BA, et al: Direct hysteroscopic observation to document the reasons for abnormal bleeding secondary to submucous myoma. *J Gynecol Surg*, 1989;5:149.

10. Rosenzweig BA, Baggish MS, Sze EHM: Carbon dioxide laser therapy for benign cervical tumors. *J Gynecol Surg*, 1990;6:97.

11. Sze EHM, Rosenzweig BA, Osborne NG, Baggish MS: Catheter-associated bacteriuria following gynecologic surgery. *J Gynecol Surg*, 1989;5:171.

12. Sze EHM, Rosenzweig BA, Birenbaum DL, et al: Excisional conization of the cervix uteri: A five-part review. Parts I and II. *J Gynecol Surg*, 1989;5:235.

13. Sze EHM, Rosenzweig BA, Birenbaum DL, et al: Excisional conization of the uteri: A five part review. Parts III, IV and V. *J Gynecol Surg*, 1989;5:325.

14. Cohn GM, Rosenzweig BA, Adelson MD, Sze EHM: A complication associated with pneumatic compression stocking used for gynecologic surgery. *J Gynecol Surg*, 1989;5:389.

15. Rader JS, Rosenzweig BA, Spirtas R, et al: Atypical squamous cells: A case-series study of the association between Papanicolaou smear and human papillomavirus DNA genotype. *J Reprod Med*, 1991;36:291.

16. Bergman F, Rotmensch S, Rosenzweig BA, et al: The role of von Willebrand factor in preeclampsia. *Thromb Haemostas*, 1991;66:525.

17. Rosenzweig BA, Soffici AR, Thomas S, Bhatia N: Urodynamic evaluation of voiding in women with cystocele. *J Reprod Med*, 1992;37:162.

18. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in female urology. *J Gynecol Surg*, 1991;7:11.

19. Rosenzweig BA, Hischke D, Thomas S, et al: Stress incontinence in women: Psychological status before and after treatment. *J Reprod Med*, 1991;36:835.

20. Rosenzweig BA, Bhatia NN: Temporal separation of cough-induced urethral and bladder pressure spikes in women with urinary incontinence. *Urology*, 1992;39:165.

21. Karrarn MM, Rosenzweig BA, Bhatia NN: Artificial urinary sphincter for recurrent-severe stress urinary incontinence in women: Urogynecologic perspective. *J Reprod Med*, 1993;38:791.

22. Rosenzweig BA, Bhatia NN, Nelson AL: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? *Obstet Gynecol*, 1991;77:586.

23. Rosenzweig BA: Neurological control of micturition. *J Gynecol Surg*, 1992;8:59.

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24. Ogundipe A, Rosenzweig BA, Karrarn MM, et al: Modified suburethral sling procedure for the treatment of recurrent or severe stress urinary incontinence. *Surg Gynecol Obstet*, 1992;175:173.

* Non peer review

ORIGINAL ARTICLES (Cont):

25. Rosenzweig BA, Pushkin S, Blumenfeld D, Bhatia NN: Prevalence of abnormal urodynamic test results in continent women with severe genitourinary prolapse. *Obstet Gynecol*, 1992;79:539.

26. Rosenzweig BA: Genitourinary prolapse and lower urinary tract dysfunction. *Int Urogynecol J*, 1993;4:296.

27. Regan MA, Rosenzweig BA: Vulvar carcinoma in pregnancy: A case report and literature review. *Am J Perinatal*, 1993;10:334.

28. Font GE, Brill AI, Stuhldreher PV, Rosenzweig BA: Endoscopic management of incidental cystotomy during operative laparoscopy. *J Urol*, 1993;149:1130.

*29. Marcovici I, Rosenzweig BA, Brill AI, Khan M, Scommegna A: Cervical pregnancy: Case reports and a current literature review. *Obstet Gynecol Surv*, 1994;49:49.

30. Norton P, Karram M, Wall LL, Rosenzweig BA, et al: Randomized double-blind trial of terodiline in the treatment of urge incontinence in women. *Obstet Gynecol*, 1994;84:386

31. Marcovici I, Rosenzweig BA, Brill AI, Scommegna A: Colchicine and post inflammatory adhesions in a rabbit model: A dose response study. *Obstet Gynecol*, 1993;82:216.

32. Baggish, MS, Brill AI, Rosenzweig BA, et al: Fatal acute glycine and sorbitol toxicity during operative hysteroscopy. *J Gynecol Surg*, 1993;9:137.

33. Rosenzweig BA, Bolina PS, Birch L, et al: Location and concentration of estrogen, androgen, and progesterone, and androgen receptors. in the bladder and urethra of the rabbit. *Neurourol Urodynam*, 1995;14:87.

34. Rosenzweig BA, Even AH, Scotti RJ: The state of resident education in urogynecology. *Int Urogynecol J*, 1995;6:18.

*35. Rosenzweig BA, Brill AI: Laparoscopic colposuspension operation, *Pro. J Gynecol Surg*, 1994;10:203.

36. Rosenzweig BA: Severe genital prolapse and its relationship to detrusor instability. *Int Urogynecol J*, 1995; 6:86.

37. Mauck C, Glover L.H., Miller E, Allen S, Archer DF, Blumenthal P, Rosenzweig BA et al: Lea's Shield: A phase 1 study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. *Contraception*, 1996; 53:329.

38. Rosenzweig BA, Even A, Budnick LE: Observations of scanning electron microscopy detected abnormalities of untreated latex condoms. *Contraception*, 1996; 53:49.

Bruce A. Rosenzweig, MD

*** Non peer review**

Bruce A. Rosenzweig
1725 W. Harrison, Suite 358
Chicago, IL 60612
312-942-6440 Office
312-942-6438 Fax

To Whom It May Concern:

From Bruce A. Rosenzweig, M.D.

Please note the following fees for expert opinion \$750.00 per hour for review of medical records and conference, \$1,500.00 per hour for deposition, and \$10,000.00 for trial testimony plus travel and hotel expenses. Please forward a **retained amount of \$15,000.00** payable to Dr. Bruce Rosenzweig to be sent with medical records (Tax ID# 201637125). Payment may be mailed to the address listed. Should you have any questions please call the office.

Sincerely,

/Bruce Rosenzweig/
Bruce A. Rosenzweig, M.D.

EXHIBIT B

**Testimonial History
of
Bruce Alan Rosenzweig, M.D.
2009 to Present**

Donald Budke v. Becky Simpson, M.D.
Court Case No. 10CM-CC00085
Missouri Circuit Court, 26th Judicial Circuit

Roxann Comried v. Thomas Getta, M.D., *et al.*
Court Case No. LA CV062272
Linn County District, Cedar Rapids, IA

Barbara Duckworth v. American Medical Systems, Inc.
Court Case No. 201137645
Texas District Court, Harris County, TX

Mary Ann Grady v. Jorge Romero, M.D.
Court Case No. CV-2011-10-5610
Ohio Common Pleas Court, Summit County, OH

Beverly Green v. Fitzgibbon Hospital
Court Case No. 08SA-CV00057
Missouri Circuit Court, 15th Judicial Circuit

Sandra L. Greene v. Lia D. Shorter, M.D., *et al.*
Court Case No. CL10000246-00
Fredericksburg Circuit Court, Fredericksburg, VA

Brooke Hollan v. Daniel Gehlbach, M.D.
Court Case No. 09CV02184
Johnson County District Court, KS

Tammy Jefferson, *et al.* v. Greater Washington Medcenter, LLC
Court Case No. CAL09-15527
Circuit for Prince George's County, MD

Mary King v. Michael Heit, M.D.
Court Case No. 13-CI-003843
Jefferson County, KY

Mary Labbe v. Summa Hospital System
Court Case No. CV-2010-11-7805
Ohio Common Pleas Court, Summit County, OH

Christy McKinney v. Summa Health System
Court Case No. CV-2011-10-5843
Ohio Common Pleas Court, Summit County, OH

Melissa Mills v. Parag Patel, M.D.
Court Case No. 05-CI-02315
Circuit Court, Boone County, KY

Judith Nash v. Kianoush Khaghany, *et al.*
Court Case No. Unknown
Michigan Circuit Court, 38th Judicial Circuit, MI

Deborah O'Donnell v. Antoinette Berkley, M.D.
Court Case No. 000971/2007
Supreme Court of New York, 9th Judicial District NY

Patricia Pater v. Mercy Health System
Court Case No. 10LA000347
Illinois Circuit Court, 22nd Judicial Circuit, IL

Marilyn Pitton, *et al.* v. Kim Josen, M.D., *et al.*
Court Case No. CV2010-050204
Arizona Superior Court, Maricopa County, AZ

Marie Skelnik v. Donald C. Whiteside, M.D.
Court Case No. 08-CVS-3683
Superior Court, Mecklenburg County, IL

Mason Smith v. John Payne, M.D.
Court Case No. 49D04-0511-CT-42869
Marion County Superior, Indianapolis, IN

Noshay v. Northwestern Medical Center
Court Case No. 10 L 004822
Cook County, IL

Tara Mills v. Todd P. Berner, M.D.
Court Case No. Unknown
Virginia

Christine A. Warner v. Thomas W. Hinz
Court Case No. Unknown
Georgia

Lewis v. Ethicon TVT
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Deposition 11/01/2013

Elizabeth Guterrez v Westlake Hospital et. al
Court No. 09 L 4276
Case No. 2010013165 (Illinois either Cook or Du Page county)
Deposition 11/21/2013

Lewis v Ethicon TVT
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Trial 02/11/2014

Huskey v. Ethicon TVT-O
Case # 2: 12 – CV – 09972
U. S. District Court Southern District of West Virginia
Deposition 3/25/14

Martinez v AMS and Endo Pharmaceuticals
Cause No. DC-13-13098
District Court of Harris County, Texas
Deposition 3/31/2014

Blankenship & Pugh v Boston Scientific Corp
Case No. 2:13-cv-22906 and 01565
U. S. District Court Southern District of West Virginia
Deposition 6/09/2014

Stamper v The Christ Hospital et al
Case No. A 1205079
Hamilton County, Ohio
Deposition 6/18/2014

Carter v Glazerman, Tampa General Hosp
Case No.: 12-CA-009942
Hillsborough County, Florida
Deposition 7/03/2014

Huskey v Ethicon TVT-O
Case #2: 12 –CV – 09972
U. S. District Court Southern District of West Virginia
Trial Testimony 8/25-26/2014

Corbet v Ethicon TVT-R
Case #291
Docket No. ATL-L-2911-13
Superior Court of New Jersey, Atlantic County
Deposition 8/29/2014

Ramirez v Ethicon TVT-O
Civil Action # 2012-CI-18690
District Court 438th Judicial District, Bexar County, Texas
Deposition 10/11/2014

MDL v CR Bard Align
MDL No. 2187
U. S. District Court Southern District of West Virginia
Deposition 10/29/2014

Covington et al v Bard
MDL No 2187
Case # 2:12 cv-05114
U. S. District Court Southern District of West Virginia
Deposition 10/30/2014

Green et al v Bard
MDL No 2187
Case # 2:13 cv-30766
U. S. District Court Southern District of West Virginia
Deposition 10/31/2014

Tyree et al v Boston Scientific Corp Obtryx
MDL No 2326
Case # 2:12 – cv – 08633
U. S. District Court Southern District of West Virginia
Trial Testimony 11/4/2014

MDL v Boston Scientific Corp Advantage/Lynx
MDL No 2325 – Advantage
U. S. District Court Southern District of West Virginia
Deposition 11/24/2014

Brock et al v Bard
MDL No 2187
Case # 2:12-cv-05114
U. S. District Court Southern District of West Virginia
Deposition 11/29/2014

Carlson et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/01/2014

Higginbotham et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/03/2014

Craft et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-04433
U. S. District Court Southern District of West Virginia
Deposition 12/08/2014

Collins et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-11658
U. S. District Court Southern District of West Virginia
Deposition 12/10/2014

Perry v Ethicon Abbrevio
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Deposition 12/15/2014

Spohn et al v Bard
MDL No 2187
Case # 2:13 cv-30512
U. S. District Court Southern District of West Virginia
Deposition 12/18/2014

Perry v Ethicon Abbrevio
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Trial Testimony 01/29/2015, 02/02/2015, 02/03/2015

Pantoja & Porter v CR Bard
MDL No 2187
Case # 2:14 cv-01353
U. S. District Court Southern District of West Virginia
Deposition 02/09/2015

Kern v Wagner
Case No.: 13-CA-009513
Circuit Court of the Thirteenth Judicial Circuit Hillsborough County, Florida
Civil Division
Deposition 04/02/2015

Acosta et al v CR Bard
MDL No 2187
Case # 2:13 cv-06855
U. S. District Court Southern District of West Virginia
Deposition 05/11/2015

Colletti et al v CR Bard
MDL No 2187
Case # 2:14 cv-11534
U. S. District Court Southern District of West Virginia
Deposition 05/18/2015

Brenner et al v Mentor Obtape
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 07/09/2015

Cavness v Ethicon Prosima
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Deposition 07/13/2015

Sherrer v Boston Scientific and CR Bard
Case No. 1216-CV27879 Division 15

Circuit Court of Jackson County, Missouri at Kansas City
Deposition 8/3/2015
Kilgore v American Medical Systems
Case No.:14CV01312 Division: 14
District Court of Johnson County Kansas
Civil Court Department
Deposition 8/12/2015

Suen et al v Mentor Obtape
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 09/10/2015

Cantrell v Ethicon (TVT-R)
Master Docket No. Ber-L-11575-14
Superior Court of New Jersey Law Division – Bergen County
Deposition 09/16/2015

Mullins et al v Ethicon (TVT-R Design Defect)
MDL Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 09/22/2015

Cavness v Ethicon (Prosima)
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Trial 09/24/2015

Carlson v Boston Scientific (Uphold)
MDL No 2326
U. S. District Court Southern District of West Virginia
U. S. District Court Western District of North Carolina
Trial 10/08/2015

EXHIBIT C

DOCUMENTS

DATE	DOCUMENT	BATES BEG	BATES END
3/2/1981	Guidoin Lab Notebook Page/Image	ETH.MESH.15958524	ETH.MESH.15958524
3/17/1982	Guidoin Lab Notebook Page/Image	ETH.MESH.15958396	ETH.MESH.15958399
3/23/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15955438	ETH.MESH.15955473
3/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958410	ETH.MESH.15958432
5/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958400	ETH.MESH.15958404
8/14/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958433	ETH.MESH.15958444
9/27/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958408	ETH.MESH.15958409
11/5/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958452	ETH.MESH.15958469
11/7/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958405	ETH.MESH.15958407
3/11/1985	Guidoin Lab Notebook Page/Image	ETH.MESH.15958445	ETH.MESH.15958451
5/30/1985	Memo N.R. Cholvín to Dr. R.L. Kronenthal, et al. re Protocol for 10 Year In Vivo Study of Monofilament Sutures	ETH.MESH.09746373	ETH.MESH.09746448
11/12/1987	Prolene* Explants Study Meeting Minutes 10/08/1987	ETH.MESH.12831407	
1/20/1988	Guidoin Explant Study notes	ETH.MESH.00004755	ETH.MESH.00004755
1/20/1988	Report: Quebec Explants	ETH.MESH.15144996	ETH.MESH.15144996
8/10/1990	Ten Year <i>In Vivo</i> Suture Study Scanning Electron Microscopy Five Year Report	ETH.MESH.11336474	
3/8/1991	General Program Memorandum #G91-1 from Director, Office of Device Evaluation	N/A	
10/15/1992	Seven year data for ten year Prolene study: ERF 85-219	ETH.MESH.5453719	ETH.MESH.5453727
10/15/1992	Seven year data for ten year Prolene study: ERF 85-219	ETH.MESH.9888187	
1/1/1997	Alex C. Wang "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report"	ETH.MESH.00371572	ETH.MESH.00371573
2/13/1997	Consulting & Technology Agreement between Johnson & Johnson International and Professor Ulf Ivar Ulmsten	ETH.MESH.08696050	ETH.MESH.08696055
2/13/1997	License and Supply Agreement between Johnson & Johnson International and Medscand Medical A.B.	ETH.MESH.8696084	ETH.MESH.8696134
5/16/1997	Report on Expert Meeting	ETH.MESH.12006257	ETH.MESH.12006259
6/13/1997	Ulmsten Preliminary report of Multicentre Study on TVT	ETH.MESH.12009095	ETH.MESH.12009101
8/8/1997	Cytotoxicity Risk Assessment	ETH.MESH.06852120	ETH.MESH.06852129
9/11/1997	Linsky email re TVT (Ulmsten) -510k submission	ETH.MESH.09747728	ETH.MESH.09747728
9/16/1997	PAC Meeting Review - Tension Free Vaginal Tape (TVT) Ulmsten Device	ETH.MESH.09747632	ETH.MESH.09747643
10/1/1997	Linsky C email re Recommendation not to Accelerate TVT Program	ETH.MESH.09747724	ETH.MESH.09747725
10/17/1997	Eriksson Clinical Report	ETH.MESH.00371587	ETH.MESH.00371594
1/11/1998	Presentation: Biocompatibility of ULTRAPRO by Joerg L. Holste, DVM	ETH.MESH.03658577	ETH.MESH.03658577

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1/28/1998	FDA 510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
1/28/1998	Letter from FDA granting 510(k) clearance for TVT	ETH.MESH.371503	
2/18/1998	Liu email chain re Prolene Mesh Redesign	HMRDH_ETH_0013326 1	HMRDH_ETH_001332 62
6/17/1998	Tang email chain re Prolene Mesh Update	ETH.MESH.09266659	ETH.MESH.09266660
6/23/1998	Ellington L email re Prolene Mesh for TVT	ETH.MESH.09266657	ETH.MESH.09266658
7/21/1998	Kaminski email chain re TVT Project Plan	ETH.MESH.10591870	ETH.MESH.10591870
7/30/1998	Kaminski Memo re summary of key point from US Marketing Research Study on TVT	ETH.MESH.00130934	ETH.MESH.00130941
8/17/1998	Rousseau Memo to Lessig re Prolene Mesh Re-Design	ETH.MESH.09264945	ETH.MESH.09264946
8/19/1998	Rowan Norrie discussion documents re design of new generation GyneMesh	ETH.MESH.12009027	ETH.MESH.12009035
9/7/1998	Tang email chain re Mesh 3	ETH.MESH.09266668	ETH.MESH.09266671
9/17/1998	Lessig email re PROLENE Mesh Redesign Project	ETH.MESH.07877085	ETH.MESH.07877085
9/23/1998	D Aversa email chain re Prolene Mesh Sheets Research	ETH.MESH.09266465	ETH.MESH.09266466
11/11/1998	R.Rousseau memo to Project Team re Meeting Minutes of Project Planning Meeting	ETH.MESH.9264884	ETH.MESH.9264884
3/30/1999	Gillick email chain re TVT insert	ETH.MESH.00203456	ETH.MESH.00203456
4/8/1999	Toth Memo to Copy Review Team re New Construction PROLENE polypropylene mesh Sales Aid and Demo Device	ETH.MESH.14410703	ETH.MESH.14410741
5/3/1999	Lehe email re Risebericht: TVT-Brainstorming (PD 98/5)	ETH.MESH.11283974	ETH.MESH.11283974
5/4/1999	Toth email chain re New Construction PROLENE polypropylene mesh Pre-Launch Memo w/attachment	ETH.MESH.14410846	ETH.MESH.14410851
6/9/1999	Hoepffner email chain re Trip report -- meeting with Dr. Ulstem	ETH.MESH.11283949	ETH.MESH.11283951
6/18/1999	Angelini email chain re Development Strategy	ETH.MESH.12009276	ETH.MESH.12009277
6/24/1999	Toth, JL Memo to Copy Review Team re TVT Tension-free Vaginal Pate Press Briefing Presentation	ETH.MESH.14411026	ETH.MESH.14411040
7/13/1999	Product Pointer for TVT Tension-free Vaginal Tape	ETH.MESH.03456775	ETH.MESH.03456776
7/14/1999	Hoepffner email re Marketing Requirements for TVT improvement team	ETH.MESH.12009262	ETH.MESH.12009262
8/18/1999	Rousseau email re Samples of PROLENE Mesh	ETH.MESH.09275875	ETH.MESH.09275876
9/13/1999	Lehe email chain re TVT Blue	ETH.MESH.12009257	ETH.MESH.12009257
9/13/1999	E-Mail discussing generations of mesh	ETH.MESH.9275875	
9/15/1999	Major Executive Committee Actions July 20, 1999 through September 15, 1999	ETH.MESH.04193990	ETH.MESH.04193993
10/12/1999	Ulmsten draft Consulting Agreement	ETH.MESH.12002847	ETH.MESH.12002860
10/13/1999	Angelini L email re Ulmsten Consultant Agreement	ETH.MESH.12002845	ETH.MESH.12002845
11/2/1999	TVT Detail Sheet (TVT001R)	ETH.MESH.161444	ETH.MESH.141445
11/15/1999	Ulmsten Consulting Agreement	ETH.MESH.12006763	ETH.MESH.12006783
11/15/1999	J&J Asset Purchase Agreement Medscand	ETH.MESH.5972834	ETH.MESH.5972866

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11/15/1999	Consulting Agreement between Ethicon, Inc. and Contape S.A. and Professor Ulf Ivar Ulmsten	ETH.MESH.8692673	ETH.MESH.8692696
11/17/1999	TVT Star PD 99/20 meeting notes.	ETH.MESH.5641096	ETH.MESH.5641098
11/25/1999	Emails between Richard Isenberg, Jochen Hoepffner, Axel Arnaud and Allesandro Rossetti re TVT event Dangerous Procedure/Death	ETH.MESH.3917309	ETH.MESH.3617312
12/2/1999	Biocomp risk assessment GPS revised	ETH.MESH.09346417	ETH.MESH.09346418
12/2/1999	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh	ETH.MESH.09346419	ETH.MESH.09346420
1/4/2000	Dormier email chain re LcBlanc CME Live on Medscape	ETH.MESH.09273600	ETH.MESH.09273601
4/5/2000	Angleitner email chain re TVT Product complaint w/handwritten notes	ETH.MESH.17661347	ETH.MESH.17661347
4/14/2000	Hellberg communication re Product Complaint Form	ETH.MESH.17661336	ETH.MESH.17661499
4/17/2000	Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.05529274	ETH.MESH.05529275
4/17/2000	Letter from Will Irby (Product Director) to sales representatives Failure to Disclose Adverse Risks/Complications Dangerous Procedure/Tensioning Professional Education/Training	ETH.MESH.5529274	ETH.MESH.5529275
5/26/2000	Biocompatibility Review	ETH.MESH.06852118	ETH.MESH.06852129
5/26/2000	Biocompatibility Review	ETH.MESH.6852118	ETH.MESH.6852129
6/1/2000	Surgeon's Resource Monograph	ETH.MESH.00658177	ETH.MESH.00658198
6/1/2000	Surgeon's Resource Monograph	ETH.MESH.658177	ETH.MESH.658198
6/6/2000	"Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons" prepared by Brigitte Hellhammer	ETH.MESH.05493965	ETH.MESH.05493999
6/9/2000	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016)	ETH.MESH.00160612	ETH.MESH.00160625
6/26/2000	TVT 2000626 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016) Patient Kit Letter and Ad template	ETH.MESH.160615	ETH.MESH.160625
7/7/2000	Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2001 Marketing Plan	ETH.MESH.0137272	ETH.MESH.01137293
7/7/2000	Incontinence/Pelvic Floor Management - GYNECARE TVT Tension-Free Support for Incontinence - 2001 Marketing Plan	ETH.MESH.1137272	ETH.MESH.1137293
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524
8/14/2000	TVT Professional Education Tensioning	ETH.MESH.00158559	ETH.MESH.00158590
8/14/2000	Gynecare TVT Professional Education Program	ETH.MESH.158559	ETH.MESH.158590
8/17/2000	Greg Slusser email chain re AUGS lecture/content of discussion	ETH.MESH.10216874	

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8/18/2000	Study Justification: Gynecare Clinical Research Program 2001 spreadsheet	ETH.MESH.08793648	ETH.MESH.08793648
8/21/2000	ARnaud A email chain re Pelvic floor repair Procedural Strategy	ETH.MESH.03909708	ETH.MESH.03909713
8/21/2000	Isenberb email re WOW Business Plan -- 2001, Clinical Research	ETH.MESH.08793646	ETH.MESH.08793647
8/21/2000	Emails between Axel Arnaud and Jochen Hoepffner re pelvic floor repair procedural strategy	ETH.MESH.3909708	ETH.MESH.3909713
8/28/2000	Memo Marty Weisberg to Rick Isenberg re discussion with redacted	ETH.MESH.03736578	ETH.MESH.03736578
9/6/2000	Ltt Nilsson from Zauberman re Surgeon Panel	ETH.MESH.09746615	ETH.MESH.09746617
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143697	ETH.MESH.00143699
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143700	ETH.MESH.00143702
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence" Article (TVT015) - REVIEW FOR REPRINT	ETH.MESH.143697	ETH.MESH.143699
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence Article (TVT005) - REVIEW FOR REPRINT	ETH.MESH.143700	ETH.MESH.143702
11/1/2000	Memo Marty Weisberg to Rick Isenberg re Complaint	ETH.MESH.03736932	ETH.MESH.03736932
11/1/2000	Memo from Martin Weisberg to Rick Isenberg re Complaint Failure to Disclose Adverse Risks/Complications	ETH.MESH.3736932	
11/30/2000	Emails between Rebecca E. Levine, Ph.D. (Sr. Engineer, R&D) and Jochen Hoepffner re Problem Statements from TVT Brainstorming Meeting.	ETH.MESH.5529653	
1/1/2001	Gynecare TVT Professional Education Slides	ETH.MESH.159636	ETH.MESH.159719
1/16/2001	Dormier email chain re Corporate Product Characterization December Monthly Report	HMESH_ETH_00946830	HMESH_ETH_00946838
2/6/2001	Vypro for Pelvic Floor Repair agenda	HMESH_ETH_02944363	HMESH_ETH_02944364
2/13/2001	Email Axel Arnaud to Dr Uwe re Dr Lucente/TVT Procedure Improvements/Prevention of Overstretching	ETH.MESH.03915380	ETH.MESH.03915380
4/11/2001	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Competitive Mesh Products - Product Pointer	ETH.MESH.00161129	ETH.MESH.00161130

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4/17/2001	Product Pointer: Gynecare TVT Tension-free Support for Incontinence: A Synthetic Sling with Erosion Rates No Higher Than Autologous Slings	ETH.MESH.00161131	ETH.MESH.00161132
4/19/2001	Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	ETH.MESH.1203207	ETH.MESH.1203260
4/23/2001	Ulmsten ltt Ostergard re Cannes meeting	ETH.MESH.10181921	ETH.MESH.10181922
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
5/14/2001	Design History CH1035 (bk2) - DH1036 (bk5)	ETH.MESH.02607272	ETH.MESH.02607814
6/1/2001	Hellhammer email chain re WG: TVT instructions for use	ETH.MESH.05494064	ETH.MESH.05494066
6/1/2001	Angelini L email re TVT improvements	ETH.MESH.12002601	ETH.MESH.12002601
6/4/2001	Emails re TVT recommendation from Dr. Alex Wang Frayed mesh/particle loss	ETH.MESH.3905472	ETH.MESH.3905477
6/6/2001	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang	ETH.MESH.03905472	ETH.MESH.03905477
6/7/2001	TVT 20010607 Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00144270	ETH.MESH.00144278
6/18/2001	2002-2003 US Marketing Plan for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.08798099	ETH.MESH.08798110
6/21/2001	TVT Recommendations from Dr. Wang - Meeting Minutes of June 21, 2001	HMESH_ETH.00958003	HMESH_ETH.00958005
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
6/26/2001	Luscombe email chain re TVT recommendations from Dr. Wang	HMESH_ETH_00958014	HMESH_ETH_00958015
6/27/2001	TVT 20010607 Gynecare TVR Tension-free Support for Incontinence Patient Brochure (Resubmission of materials per FDA requirement)	ETH.MESH.144270	ETH.MESH.144278
7/3/2001	Presentation: TVT Sales Force Update @ Divisional Meeting	ETH.MESH.00144304	ETH.MESH.00144331
7/6/2001	Dormier E email chain re Vypro vs Soft Prolene Mesh for Pelvic Floor Repair	ETH.MESH.17606501	ETH.MESH.17606502
8/2/2001	5-Year Press Release Draft: Long-term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support Treating Stress Urinary Incontinence	ETH.MESH.00764323	ETH.MESH.00764325
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
9/28/2001	2002 US Marketing Plan for TVT	ETH.MESH.09306898	ETH.MESH.09306910
10/1/2001	New Products Development Gynecare Products by Axel Arnaud	ETH.MESH.03909721	ETH.MESH.03909733
10/12/2001	Memo by Lynn Hall re Summary of Findings and Next Steps from 10.12.01 TVT DTC Focus Groups	ETH.MESH.1217285	ETH.MESH.1217288
10/26/2001	K012628 TVT Blue System and Accessory TVT-AA	ETH.MESH.748310	ETH.MESH.748450

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1/16/2002	Luscombe email re ALERT!!! Professional Ads for GYNECARE TVT !!!!! w/attachments	ETH.MESH.00029963	ETH.MESH.00029966
1/16/2002	Email from Brian Luscombe re ALERT!!! Professional Ads for GYNECARE TVT!!!!!!!!!!!!!!!!!!!!!! with attached TVT Sales Aid (TVT041)	ETH.MESH.29963	ETH.MESH.299996
1/28/2002	Corporate Product Characterization - Comparison of Particle Characteristics of Clear and 50% Blue PROLENE Mesh of TVT Device	ETH.MESH.02613804	ETH.MESH.02613805
1/28/2002	Particle Release Characteristics of Clear and Blue TVT Mesh Corporate Product Characterization	ETH.MESH.04384185	ETH.MESH.04384188
3/28/2002	Letter from Howard Zauberman (Ethicon) to Mr. Jan Johansson (Director, Eurosund Medical AB)	ETH.MESH.08695896	ETH.MESH.08695896
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
4/25/2002	Email Ettore Carino to Kimberly Mullarkey re FW: DTC Review	ETH.MESH.08793552	ETH.MESH.08793553
5/1/2002	"Second Generation TVT" by Axel Arnaud	ETH.MESH.03907468	ETH.MESH.03907469
6/7/2002	Email Richard Isenberg to Greg Jones, et al. re Dr Alex Wang, Taiwan--Reports of "tape rejection" with TVT	ETH.MESH.00409674	ETH.MESH.00409675
6/7/2002	Emails Richard Isenberg to Dr Wang re concerns for patient safety	ETH.MESH.03735432	ETH.MESH.03735433
6/7/2002	Emails from Richard Isenberg (Director of Medical Affairs, Gynecare Worldwide) re Dr. Alex Wang, Taiwan - Reports of "tape rejection" with TVT	ETH.MESH.409674	ETH.MESH.409675
6/10/2002	Email Mark Yale re Wang's rejections	ETH.MESH.03483690	ETH.MESH.03483693
6/26/2002	Gynecare TVT Tension-free Support for Incontinence - Tips for Speaking with your Physician	ETH.MESH.158082	
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
7/2/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961197	ETH.MESH.05961203
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7/9/2002	FDA Communication re 522 Prosima	ETH.MESH.04927339	ETH.MESH.04927340
7/18/2002	Isenbert R Note to File re TVT associated Obturator Nerve Syndrome Complaint	ETH.MESH.03736538	ETH.MESH.03736539
9/11/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961212	ETH.MESH.05961234
9/16/2002	Email Shannon Campbell to Shelley Copeland, et al. re Ft. Worth Advanced TVT dinner feedback	ETH.MESH.11773498	ETH.MESH.11773499
9/27/2002	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones	ETH.MESH.00030025	ETH.MESH.00030026
9/27/2002	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones (sales rep)	ETH.MESH.30025	
10/4/2002	Rejection of Polypropylene Tape After the Tension-Free Vaginal Tape (TVT) Procedure by Alex C. Wang, MD	ETH.MESH.00409657	ETH.MESH.00409658
10/4/2002	Report: Visit to Pr Jean de Leval	ETH.MESH.03910208	ETH.MESH.03910210

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10/4/2002	Rejection of Polypropylene Tape After The Tension-Free Vaginal Tape (TVT) Procedure, A. Wang, MD	ETH.MESH.409657	ETH.MESH.409658
10/13/2002	Emails between Martin Weisberg and Axel Arnaud re Soft Prolene and attached Clinical Expert Report: Prolene Soft (Polypropylene) Mesh	ETH.MESH.3910183	ETH.MESH.3910193
10/14/2002	"Confidential - Trans-obturator TVT - Procedure In-Out" by Axel Arnaud Product Defect	ETH.MESH.3907327	ETH.MESH.3907330
10/15/2002	Arnaud, A; Weisberg email chain originating 09/20/2002 re Soft Prolene " . . . wise to be elusive on warnings . . . "	ETH.MESH.3910175	ETH.MESH.3910177
10/16/2002	TVT 20021016 TVT - Freedom From Stress Urinary Incontinence	ETH.MESH.2169504	ETH.MESH.2619511
10/17/2002	Memo to Jacqueline Russo from Ogilvy Public Relations Worldwide re Dr. Donnica Moore Opportunity Analysis and Recommendation	ETH.MESH.766347	ETH.MESH.766349
10/23/2002	Univ De Leige, Centre Hospitalier Universitaire De Liege and Ethicon Licensing Agreement	ETH.MESH.03918253	ETH.MESH.03918264
10/31/2002	Emails between Martin Weisberg and Mark Sumeray (VP Clinical Trials) re Dr. Wang's proposal to perform histological and immunohistochemical study on biopsies taken from women with tape erosion	ETH.MESH.8793207	ETH.MESH.8793210
11/26/2002	Axel Arnaud email chain re Mini TVT - Mesh adjustment	ETH.MESH.3910418	
11/26/2002	Weisberg email chain originating 11/22/2002 re Mini TVT mesh adjustment - "... overtension is not possible and that tension free placement of the tape is not critical. . . "	ETH.MESH.3917375	ETH.MESH.3917378
12/3/2002	Email Martin Weisberg to Mark Sumeray et al. re Prolene rejection	ETH.MESH.00409670	ETH.MESH.00409670
12/13/2002	Marketing Plan TVT-O	ETH.MESH.3918352	
12/27/2002	Customer Initiated Research Grant Request (Wang)	ETH.MESH.409659	ETH.MESH.409663
1/9/2003	Corrective/Preventive Action TVT Tape	ETH.MESH.05961304	ETH.MESH.05961315
1/27/2003	DTC Focus Group Summary	ETH.MESH.00766975	ETH.MESH.00766976
1/31/2003	Tracey M Trip Report	ETH.MESH.01808311	ETH.MESH.01808318
2/5/2003	Tracey M email re Trip Report Format Mulberry 22Jan2003	ETH.MESH.01808310	ETH.MESH.01808310
2/13/2003	Presentation - Ultrasonic Slitting of TVT Mesh Technical Review	ETH.MESH.06866920	ETH.MESH.06866920
2/14/2003	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT	ETH.MESH.06873447	ETH.MESH.06873458
2/18/2003	Universite de Liege and Ethicon Licensing Agreement	ETH.MESH.15363068	ETH.MESH.15363085
2/20/2003	Arnaud A email chain re TVT complications (an Prof. Häusler)	ETH.MESH.03911107	ETH.MESH.03911108
2/20/2003	Strategic Plan Challenge	ETH.MESH.4205632	ETH.MESH.4205636

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2/28/2003	Cirelli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
3/18/2003	Osoris M email re International Convention Suggestions	ETH.MESH.00581482	ETH.MESH.00581482
3/20/2003	Strategic Plan Challenge	ETH.MESH.04205632	ETH.MESH.04205636
3/26/2003	Arnaud A email chain re Mulberry	ETH.MESH03919404	ETH.MESH03919405
4/8/2003	Notes from team meeting	ETH.MESH.858080	
4/10/2003	April 10, 2003 meeting minutes from Project Leader Dan Smith	ETH.MESH.00858110	ETH.MESH.00858111
4/10/2003	April 10, 2003 meeting minutes from Project Leader Dan Smith	ETH.MESH.858110	
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
4/14/2003	Email Cheryl Bogardus to Dan Smith and Brian Luscombe.	ETH.MESH.260591	
4/30/2003	TVOT Meeting Report	ETH.MESH.03934952	ETH.MESH.03934967
5/13/2003	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare	ETH.MESH.00030098	ETH.MESH.00030098
5/13/2003	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy	ETH.MESH.30098	
5/15/2003	Emails Brian Luscombe to Axel Arnaud et al. re: De Leval Publication	ETH.MESH.03918552	ETH.MESH.03918553
5/15/2003	Emails between Brian Luscombe, Axel Arnaud and Janice Burns re De Leval Publication	ETH.MESH.3918552	
5/29/2003	Study spreadsheet	ETH.MESH.00863841	ETH.MESH.00863842
5/29/2003	DHF 25 1-323 CE Mark of TVT - AA Kit.pdf	ETH.MESH.02222437	ETH.MESH.02222656
6/6/2003	LeTreguilly L email chain re TVT Serious complication	ETH.MESH.03907853	ETH.MESH.03907854
6/6/2003	Emails between Sascha Blessin (Sr. Marketing Mng., Gynecare Europe/Germany) and Laure Le Treguilly (Gynecare Marketing Mng.) re TVT - Serious complication Dangerous Procedure/Death	ETH.MESH.3907853	ETH.MESH.3907854
6/11/2003	Russo-Jankewicz email re Stressful Secrets press release crosses wire	ETH.MESH.00764215	ETH.MESH.00764216
6/19/2003	Eltrasonic Slitting of TVT Mesh presentation	ETH.MESH.00586018	ETH.MESH.00586019
6/20/2003	Leibowitz Tensile Properties, Morphology Test Report	ETH.MESH.01279975	ETH.MESH.01279977
6/20/2003	Leibowitz Tensile Properties, Morphology Test Report	ETH.MESH.05442881	ETH.MESH.05442883
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
6/30/2003	Presentation: Marketing Plan VOC by Boris Batke Project Edelweiss	ETH.MESH.05585033	ETH.MESH.05585053
7/7/2003	Email from Brian Luscombe re "Urethral erosion may occur with any sling material" Article (TVT063)	ETH.MESH.30372	ETH.MESH.30373

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7/9/2003	Email Martin Weisberg to Terry Courtney re TVT question	ETH.MESH.03715978	ETH.MESH.03715980
7/11/2003	Email Brian Luscombe to Steve Bell, et al. re Ulmsten opinion on Mulberry	ETH.MESH.06884249	ETH.MESH.06884250
7/17/2003	Arnaud email re Mulberry IFU	ETH.MESH.00865147	ETH.MESH.00865147
7/18/2003	Email Brian Luscombe to Dan Smith et al. re Design Validation	ETH.MESH.00864085	ETH.MESH.00864087
7/21/2003	Ciarrocca email chain re Gynemesh holding force in tissue	ETH.MESH.03919143	ETH.MESH.03919144
7/21/2003	Email Janice Burns to Dan Smith, et al. RE: Design Validation	ETH.MESH.06880021	ETH.MESH.06880023
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102
7/24/2003	Emails between Dan Smith and Vincent Lucente re TOVT development	ETH.MESH.864101	
8/8/2003	Email from Laura Angelini re Transient Leg Pain with MULBERRY		
8/14/2003	Kammerer G email chain re Aug 11 program	ETH MESH 01220661	ETH MESH 01220663
8/15/2003	Email Brian Luscombe re Mulberry Final DRAFT #1	ETH.MESH.00260739	ETH.MESH.00260744
8/18/2003	Kammerer email chain re TVT Mesh Fraying	ETH.MESH.01220693	ETH.MESH.01220697
8/18/2003	Emails re Dr. Alex Wang's complaints re frayed and uneven mesh	ETH.MESH.1220693	
8/21/2003	Cosson, et al, <i>Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?</i> Int Urogynecol J (2003) 14: 169-178	ETH.MESH.15598	ETH.MESH.15607
8/25/2003	Email Martin Weisberg to Dan Smith, et al. re Mulberry Final Draft #1	ETH.MESH.03715869	ETH.MESH.03715876
9/6/2003	Email Martin Weisberg to Marianne Kaminski re TVT Response for Peggy Norton MD	ETH.MESH.03738468	ETH.MESH.03738470
9/6/2003	Emails between Martin Weisberg and Dr. Peggy Norton re TVT Underreporting of complications Professional Education/Training	ETH.MESH.3738466	ETH.MESH.3738467
9/8/2003	Arnaud A email chain re TVT complication	ETH.MESH.03928696	ETH.MESH.03928697
10/1/2003	Gynecare TVT AUGS & Competitive Update - copy review submission form	ETH.MESH.14415287	ETH.MESH.14415309
10/2/2003	de Leval, J, "Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out"	ETH.MESH.06880472	ETH.MESH.06880478
10/2/2003	Arnaud email re Pr de LEVAL expenses	ETH.MESH.15928345	ETH.MESH.15928345
10/23/2003	Design Input Strategy Project Mulberry by Dan Smith and Janice Burns	ETH.MESH.259269	ETH.MESH.259274

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10/25/2003	Letter from Martin Weisberg (Director, Medical Affairs, Gynecare) - 7 Year Data Indicates Strong Continued Safety and Effectiveness For GYNECARE TVT Tension-free Support for Incontinence	ETH.MESH.524444	ETH.MESH.524445
10/30/2003	Presentation: TVT Patent Portfolio by Andrea Slater-Tomko	ETH.MESH.5236223	ETH.MESH.5236255
11/18/2003	Weisberg Memo re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
11/18/2003	Memo by Martin Weisberg re Mesh Fraying for TVT Devices Inadequate testing	ETH.MESH.541379	ETH.MESH.541380
11/20/2003	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study	ETH.MESH.01222584	ETH.MESH.01222705
11/20/2003	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study	ETH.MESH.02614396	ETH.MESH.02614399
11/26/2003	Emails between Martin Weisberg and Barbara McCabe re leVal	ETH.MESH.3715571	ETH.MESH.3715573
12/8/2003	Attachment V 510(k) Summary Gynecare TVT Obturator	ETH.MESH.00019863	ETH.MESH.00019924
12/9/2003	3.4.4 DDSA version 0 - Memo Gary Borkes to DHF for the Gynecare TVT-Obturator re TVT-O Version 0 Design Risk Assessment Evaluation	ETH.MESH.00222366	ETH.MESH.00222395
1/1/2004	Only Gynecare TVT Has Long-term Results You Can See	ETH.MESH.00160813	ETH.MESH.00160821
1/1/2004	2004 Performance & Development Plan for Patricia Hojnoski	ETH.MESH.7931874	ETH.MESH.7931886
1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
1/16/2004	Smith D email re Dedications	ETH.MESH.06164409	ETH.MESH.06164410
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
1/29/2004	Gynecare TVT Introduction to cross train the Uterine	ETH.MESH.05793690	ETH.MESH.05793693
2/19/2004	Smith D email re TVT-O recognition Submission	ETH.MESH.06892171	ETH.MESH.06892172
2/19/2004	Dan Smith email re TVT-O recognition Submission	ETH.MESH.6892171	
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
2/27/2004	Smith, D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.863391	ETH.MESH.863393
3/1/2004	Burns email chain re Mulberry IFU	ETH.MESH.00866317	ETH.MESH.00866318
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
3/2/2004	Burns email chain re Remainder on BLUE mesh!	ETH.MESH.13204333	ETH.MESH.13204334
3/2/2004	Email from Steve Bell (Director Marketing Europe) to Sales & Marketing Team re Reminder on Blue Mesh - frayed mesh/particle loss	ETH.MESH.865322	ETH.MESH.865323
3/3/2004	Copy Review Submission Form - Inside Gynecare Vol II, #5	ETH.MESH.14416182	ETH.MESH.14416221
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407

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3/10/2004	TVT 20040310 What you Can do about it... TVT-Stress Urinary Incontinence in Women	ETH.MESH.02619601	ETH.MESH.02619616
3/17/2004	Gynecare Copy Review Submission Form submitted by Giselle M. Bonett re Gynecare Gynemesh PS	ETH.MESH.14416076	ETH.MESH.14416081
3/29/2004	de Leval J memo	ETH.MESH.02180759	ETH.MESH.02180761
4/14/2004	TVT sales piece (TVT041R3)	ETH.MESH.00658058	ETH.MESH.00658065
4/14/2004	Copy Review Submission Frmm - MoniTorr, TVT-O, CORLINK, ProPen, MultiPass	ETH.MESH.14416898	ETH.MESH.14416959
4/14/2004	TVT sales piece (TVT041R3) Only Gynecare TVT Has Long-Term Results You Can See...and Believe Pore size Fibrotic bridging/scar plate/contraction/shrinkage Chronic inflammatory response	ETH.MESH.658058	ETH.MESH.658065
4/19/2004	LIMS Project #: BE-2004-912 Study Report	ETH.MESH.00158286	ETH.MESH.00158288
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813
4/27/2004	LIMS Project #: BE-2004-916	ETH.MESH.00862206	ETH.MESH.00862208
5/4/2004	Schiaparelli J email re Marlex Experience	ETH.MESH.05918776	ETH.MESH.05918776
5/21/2004	Email from David Robinson MD to Dan Smith regarding deLeval's Babcock technique	ETH.MESH.864413	
6/30/2004	Leibowitz email re Comparison of TVT Mesh to Meshes from Competitive Devices	ETH.MESH.00863692	ETH.MESH.00863694
7/21/2004	Arnaud A email chain re TVT Erosion	ETH.MESH.03910799	ETH.MESH.03910800
7/21/2004	Emails between Axel Arnaud, Janice Burns and Olivia Derwin (Acct. Manager, Gynecare) re TVT Erosion?	ETH.MESH.3910799	ETH.MESH.3910800
7/22/2004	Email Walji to Bogardus, et al. re ICS / Paris - Gala Invitee List	ETH.MESH.02201463	ETH.MESH.02201467
8/16/2004	Email James McDivitt to Thomas Barbolt re Autoclaving PROLENE	ETH.MESH.05456117	ETH.MESH.05456118
8/17/2004	Email from Dan Smith to Katrin Elbert re IFU changes	ETH.MESH.01814740	ETH.MESH.01814741
8/17/2004	Burns J email chain re TVT-O	ETH.MESH.06881576	ETH.MESH.06881580
8/18/2004	Mahar K email re Dr. Jensen Follow UP	ETH.MESH.06884516	ETH.MESH.06884517
8/27/2004	Email Marianne Kaminski to Amy Vie, et al. re 2004 budget - PE August adjustments	ETH.MESH.05795299	ETH.MESH.05795300
9/7/2004	Walji email chain re Pelvic Floor Monthly - August Report - Next Gen Materials Progress	ETH.MESH.00681364	ETH.MESH.00681366
9/11/2004	Gynecare University Program Las Vegas, Nevada	ETH.MESH.08107153	ETH.MESH.08107155
9/16/2004	Campbell, S email chain re Ongoing TVT-O Action Items	ETH.MESH.00864503	ETH.MESH.00864507
9/16/2004	Campbell email chain re Ongoing TVT-O Action Items	ETH.MESH.06884728	ETH.MESH.06884732
9/16/2004	Emails between Shannon Campbell (sales rep) and Dan Smith re ongoing TVT-O action items	ETH.MESH.864503	ETH.MESH.86507
9/23/2004	"Professional Education for GYNECARE TVT Physician Training" updated draft by Marianne Kaminski	ETH.MESH.03624321	ETH.MESH.03624322

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9/23/2004	"Professional Education Guidance" for Gynecare TVT Physician Training, updated draft by Marianne Kaminski	ETH.MESH.3624321	ETH.MESH.3624322
9/24/2004	Gyncecare Mega Course Uterine Health Urodynamics Incontinence and Pelvic Floor Repair and the OB/GYN Surgeon, Urogynecologist and Urologist	ETH.MESH.05795309	ETH.MESH.05795315
10/7/2004	Sales School Presentation: Gynecare Professional Relations and Professional Education "Educating Customers Worldwide to improve the lives of women!"	ETH.MESH.00031538	ETH.MESH.00031560
10/18/2004	Cancellation Agreement between Ethicon, Inc., Contape S.A., and the estate of Professor Ulf Ivar Ulmsten	ETH.MESH.8692670	ETH.MESH.8692672
11/1/2004	Smith D email re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
11/1/2004	Dan Smith email chain re Update from Oct 27 cadaver lab	ETH.MESH.5548122	
11/2/2004	Email from Patty Lancos to Manuel Castro and Dan Smith re FDA Prep	ETH.MESH.01813975	ETH.MESH.01813978
11/5/2004	MedWatch Report	ETH.MESH.03589219	ETH.MESH.03589220
11/10/2004	Telefax from Basso Sibyll to David Menneret (Complaint investigator/Regulatory contact) re Dr. Eberhard	ETH.MESH.2180828	ETH.MESH.2180830
11/10/2004	Presentation by Boris Batke (Ethicon R&D): The (clinical) argument of lightweight mesh in abdominal surgery	ETH.MESH.5479411	
11/12/2004	Email from David Menneret to Dan Smith and others re Mesh Fraying: DR. EBERHARD letter	ETH.MESH.2180826	ETH.MESH.2180827
11/12/2004	Translation of PD Doctor Eberhard's letter of 18.10.04	ETH.MESH.2180833	
11/30/2004	7 year Data Press Release New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates	ETH.MESH.155598	ETH.MESH.155600
12/6/2004	Development Contract TVT-Next (TVT _x)	ETH.MESH.01217673	ETH.MESH.01217690
12/8/2004	TVT 20041208 Gynecare TVT Tension-free Support for Incontinence Patient Brochure reprint /Robin Osman	ETH.MESH.08003197	ETH.MESH.08003212
12/10/2004	Emails between Steve Bell, Kevin Mahar and Dan Smith re VOC on Laser cut mesh - underreporting of complications	ETH.MESH.1811770	ETH.MESH.1811772
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
1/3/2005	2005 Variable Compensation Plan Sales Representative	ETH.MESH.05768705	ETH.MESH.05768712
1/5/2005	Email Laura Angelini to Ronnie Toddywala, et al. re Important Laser cut mesh Update	ETH.MESH.00440005	ETH.MESH.00440007

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1/11/2005	Email Katrin Elbert re TVT-O IFU change	ETH.MESH.00261818	ETH.MESH.00261818
1/17/2005	Kammerer email re Presentation #1	ETH.MESH.00585220	ETH.MESH.00585220
1/18/2005	Hojnoski Personnel File	ETH.MESH.07931874	ETH.MESH.07931886
1/19/2005	Presentation: Mechanical vs. "Machine"-cut Mesh	ETH.MESH.02248778	ETH.MESH.02248778
1/19/2005	Presentation: Mechanical vs. "Machine"-cut Mesh	ETH.MESH.2248778	
1/27/2005	Smith email re TVT-U	ETH.MESH.05553782	ETH.MESH.05553782
1/28/2005	Carino email chain re Recommendations for Non-Sales and Marketing Glamour Trip Award	ETH.MESH.08792936	ETH.MESH.08792938
1/30/2005	Castillo email chain re Oscar -- The latest fiasco	ETH.MESH.11474337	ETH.MESH.11474337
2/1/2005	Presentation: TVT Bonnie Blair Campaign	ETH.MESH.00524907	ETH.MESH.00524907
2/1/2005	Presentation: TVT Bonnie Blair Campaign	ETH.MESH.524907	
2/2/2005	TVT Mailers for Physicians	ETH.MESH.00162420	ETH.MESH.00162421
2/2/2005	Gynecare TVT Mesh brochure copy review submission form	ETH.MESH.14410478	ETH.MESH.14410484
2/11/2005	TVT IFU through	ETH.MESH.02340471	ETH.MESH.02340503
2/16/2005	Copy review submission form - Hernia ad; Proceed Mesh. ULTRAPRO mesh and PROLENE hernia system	ETH.MESH.14409737	ETH.MESH.14409741
2/28/2005	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment	ETH-03531	ETH-03567
3/1/2005	Email Charlotte Owens to Carol Holloway re Medical Review file #30005136	ETH.MESH.03574916	ETH.MESH.03574919
3/10/2005	Berger L Itt Wallingford J re Unknown TVT Ref #3005146	ETH.MESH.03499528	ETH.MESH.03499529
3/10/2005	Next Generation Mesh Discussion	ETH.MESH.05245427	ETH.MESH.05245428
3/15/2005	Oldehr M email chain re Kalamazoo TVT Business at Risk	HMESH_ETH_01876389	HMESH_ETH_01876393
3/24/2005	Hunsicker email chain re ICS Submission	ETH.MESH.06828907	ETH.MESH.06828909
4/5/2005	Email Charlotte Owens to Carin Rassier re Complaint 30005255	ETH.MESH.03575061	ETH.MESH.03575061
4/12/2005	Kammerer, G email chain re Ultrapro	ETH.MESH.03915588	ETH.MESH.03915590
4/13/2005	TVT 20040413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman	ETH.MESH.00658421	ETH.MESH.00658429
4/13/2005	Barbara McCabe email re Sheath Sales Tool	ETH.MESH.00994917	ETH.MESH.00994918
4/13/2005	Sunoco C4001 Polypropylene Homopolymer - MSDS	ETH.MESH.02026591	ETH.MESH.02026595
4/13/2005	Corporate Product Characterization Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs Mechanical-Cut Version 1	ETH.MESH.02614599	ETH.MESH.02614603
4/13/2005	Holste, J email chain re Ultrapro	ETH.MESH.04020134	ETH.MESH.04020137
4/13/2005	Barbolt, T email chain re Ultrapro	ETH.MESH.05469908	ETH.MESH.05469912
4/13/2005	Emails Marianne Kaminski to Paul Parisi, et al. re Q1 PE results REVISED	ETH.MESH.05795322	ETH.MESH.05795324

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4/13/2005	TVT 20050413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman	ETH.MESH.658421	ETH.MESH.658429
4/13/2005	Barbara McCabe email re Sheath Sales Tool	ETH.MESH.994917	
4/14/2005	Toddywala, R email chain re Ultrapro	ETH.MESH.03915567	ETH.MESH.03915572
4/29/2005	Komamycky P email chain re Bio compatibility samples	ETH.MESH.05549696	ETH.MESH.05549700
5/5/2005	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut Study (LIMS#BE-2005-1920) Version 3	ETH.MESH.06696367	ETH.MESH.06696379
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
5/25/2005	TVT Retropubic Issue Report No. 30005181	ETH.MESH.02627466	ETH.MESH.02627466
6/1/2005	Oldelehr email re gynecology vs urology	ETH.MESH.08107933	ETH.MESH.08107933
6/6/2005	Zaddem V email chain re MINT: 6/2/05 Materials Advisory meeting minutes	ETH.MESH.02020712	ETH.MESH.02020713
6/28/2005	Objectives for Jennifer - May-August	ETH.MESH.19356913	ETH.MESH.19356915
7/19/2005	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00412260	ETH.MESH.00412269
7/25/2005	Pariente, J-L, "An independent biomechanical evaluation of commercially available suburethral slings," <u>Issues in Women's Health</u> , 2003; 9-12	ETH.MESH.1221055	ETH.MESH.1221058
8/16/2005	London Brown A email re TVT Laser Cut Mesh	ETH.MESH.00525573	ETH.MESH.00525573
8/23/2005	Draft Clinical Expert Report Gynecare TVT Secur System by Martin Weisberg, Senior Medical Director	ETH.MESH.03905059	ETH.MESH.03905072
8/23/2005	Email Paula Evans to Sungyoon Rha et al. re TVT Laser Cut Value Proposition and Forecast	ETH.MESH.04985249	ETH.MESH.04985252
8/23/2005	Draft Clinical Expert Report for TVT SECUR by Martin Weisberg, Senior Medical Director	ETH.MESH.3905059	
8/23/2005	Evans email chain re TVT Laser Cut Value Proposition and Forecast - TVT Classic roping/sheath issues - failure to warn	ETH.MESH.4985249	
8/24/2005	Gynecare TVT Professional Education Slides	ETH.MESH.00525322	ETH.MESH.00525400
8/24/2005	Gynecare TVT Professional Education slides	ETH.MESH.525322	ETH.MESH.525400
8/26/2005	TVT Obturator Complaint Note to File	ETH.MESH.03736967	ETH.MESH.03736968
8/29/2005	Physician form letter	ETH.MESH.12933182	ETH.MESH.12933183
9/1/2005	Consulting Agreement B-1 between Brian J. Flynn and Ethicon	ETH.MESH.03605398	ETH.MESH.03605402
10/12/2005	Letter from Carol Holloway (Product Complaint Analyst) to Herve Fournier (Ethicon France) re TVT tape particles	ETH.MESH.3535750	
10/31/2005	Presentation: Investigator Initiated Study Process by Kimberly Hunsicker, MSN, CRNP (Regional Manager, Clinical Operations) - Inadequate testing	ETH.MESH.311832	ETH.MESH.311848
11/4/2005	Rousseau, R email chain re Gynemesh PS w/Monocryl	ETH.MESH.09268506	ETH.MESH.09268508

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11/16/2005	Email from Carolyn Brennan (Project Manager, Worldwide Customer Quality) re Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.875647	ETH.MESH.875649
11/18/2005	Emails between Carolyn Brennan (Project Manager, Worldwide Customer Quality), Patricia Hojnoski (Regulatory Affairs), Martin Weisberg (Senior Medical Director) and Dan Smith (Gynecare R&D) re Updated TVT and TVT-O Complication Rates 11-15-05 Underreporting of complications	ETH.MESH.5560961	ETH.MESH.5560963
11/21/2005	Emails re !!!!GREAT NEWS FOR TVT LASER CUT MESH!!!! Frayed mesh/particle loss	ETH.MESH.301741	ETH.MESH.301742
11/24/2005	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
11/25/2005	Silimkhan presentation Evaluation of Gynecare Prolene Meshes	ETH.MESH.00586019	ETH.MESH.00586019
12/2/2005	CER - Gynecare TVT Secur System	ETH.MESH.04385229	ETH.MESH.04385245
12/13/2005	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
12/14/2005	Email from David Robinson (Medical Director) re Risk/Benefit Analysis for TVT SECUR Clinical Expert Report	ETH.MESH.823660	
12/19/2005	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/19/2005	Emails from Kevin Mahar re FW: Lazer cut mesh (Ex. T-3164)	ETH.MESH.687819	
12/20/2005	Presentation: SUI, A Primary Care Perspective	ETH.MESH.995657	
12/21/2005	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
1/15/2006	Miller email chain re GYNECARE TVT Latest Complication Data	ETH.MESH.00134498	ETH.MESH.00134499
1/15/2006	Email Dennis Miller to Dharini Amin et al. re Gynecare TVT Latest Complication Data	ETH.MESH.00756887	ETH.MESH.00756888
1/15/2006	Emails between Dharini Amin (Product Director Continence Health) and Dr. Dennis Miller re GYNECARE TVT Latest Complication Data - underreporting of complications	ETH.MESH.134498	ETH.MESH.134499
1/19/2006	Van Dijk email chain re Ti-mesh research	ETH.MESH.03908029	ETH.MESH.03908031
1/20/2006	London Brown email chain re TVT U Completion Report Version 3	ETH.MESH.01218594	ETH.MESH.01218596
1/26/2006	Vandenburgh 2005 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000315	ETHMESH.OHARA.00000321
1/31/2006	Arnaud A email chain re TVT - TVT-O Specifications	ETH.MESH.03911712	ETH.MESH.03911715
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
2/6/2006	Robinson email chain re TVT complications	ETH.MESH.00847536	ETH.MESH.00847536
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
2/20/2006	Arnaud email chain re TVM discussions	ETH.MESH.03929173	ETH.MESH.03929177

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2/23/2006	Memo Dan Lamont re TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis	ETH.MESH.00302390	ETH.MESH.00302392
2/23/2006	Email Cindy Crosby to Mark Yale, et al. re MHRA request - TVT blue pigment risk assessment	ETH.MESH.00330760	ETH.MESH.00330764
2/23/2006	TVT-Base & TVT-) Review for Laser Cut (LCM) Risk Analysis	ETH.MESH.302390	ETH.MESH.30292
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary	ETH.MESH.10984358	ETH.MESH.10984359
2/27/2006	Bonet email re Prolift Anatomy Images	ETH.MESH.00782152	ETH.MESH.00782152
2/28/2006	Robinson email re tvf - training	ETH.MESH.00846523	ETH.MESH.00846523
3/1/2006	Mahar email chain re Urgent Request: Revised TVt Complication data 2-9-06	ETH.MESH.00134029	ETH.MESH.00134031
3/2/2006	Email Dr. James Hart to David Robinson re tvf o training	ETH.MESH.04122262	ETH.MESH.04122264
3/6/2006	Kammerer memo re Elongation Characteristics of Laser Cut PROLENE Mesh for TVT	ETH.MESH.01222075	ETH.MESH.01222079
3/6/2006	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR	ETH.MESH.03358398	ETH.MESH.03358402
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
3/7/2006	Weisberg, Robinson Clinical Expert report	ETH.MESH.01784823	ETH.MESH.01784828
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619
3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673
3/10/2006	Urology University March 10-11, 2006	ETH.MESH.11920108	ETH.MESH.11920110
3/13/2006	Holste J email chair re Mesh and Tissue Contraction in Animal	ETH.MESH.05446127	ETH.MESH.05446128
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
3/22/2006	TVT Slim Jim (TVT107)	ETH.MESH.00169748	ETH.MESH.00169751
3/29/2006	Email Daniel Lamont to Jacqueline Flatow re TVT LCM - design inputs	ETH.MESH.00302181	ETH.MESH.00302184
3/30/2006	Gadot email chain re Laser Cut Mesh Positioning (Redacted)	ETH.MESH.00700348	ETH.MESH.00700350
3/30/2006	Email Mark Yale re TVT laser cut equivalency	ETH.MESH.01945854	ETH.MESH.01945854
3/30/2006	Gadot email re Laser Cut Mesh Positioning (Redacted)	ETH.MESH.700348	ETH.MESH.700350
4/2/2006	Mahar K email chain re Laser Cut Mesh Positioning	ETH.MESH.06040171	ETH.MESH.06040173
4/7/2006	TVT IFU through	ETH.MESH.05222673	ETH.MESH.05222705
4/10/2006	An evaluation of the Gynecare TVT Tension-free support for incontinence and Gynecare TVT Obturator system tension-free support for incontinence with laser cut mesh - Amendment 1	ETH.MESH.10302268	ETH.MESH.10302279

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4/17/2006	Kammerer G Memo re Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh	ETH.MESH.14450438	ETH.MESH.14450442
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
4/22/2006	TVT: Insights into Making of a Revolution by Sheri Dodd, VP, Worldwide, Health Economics and Reimbursement	ETH.MESH.6859904	
4/25/2006	Minute - Tactile appraisal of TVT LCM & LCM-MC both vs MCM	ETH.MESH.06696589	ETH.MESH.06696592
4/26/2006	Damotte M email chain re RE: Laser cut TVT - Surgeon's Preference Evaluation	ETH.MESH.10302266	ETH.MESH.10302267
5/1/2006	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)	ETH.MESH.03358217	ETH.MESH.03358224
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
5/9/2006	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990
5/9/2006	Mesh Development Timeline	ETH.MESH.1816990	
5/9/2006	Email from Gene Kammerer (Engineering Fellow, R&D) re Particle Loss on TVT	ETH.MESH.585802	
5/18/2006	Class III License Amendment Application	ETH.MESH.10630324	ETH.MESH.10630449
5/22/2006	Sungyoon Rha email re First Human Use - Surgeon preference Questionnaire	ETH.MESH.00584175	ETH.MESH.00584178
5/22/2006	Sungyoon Rha email re First Human Use - Surgeon preference Questionnaire	ETH.MESH.10372553	
5/22/2006	"World Premiere" as Ethicon Women's Health & Urology with special guest Bonnie Blair	HMESH_ETH_01840151	HMESH_ETH_01840152
5/31/2006	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: D	ETH.MESH.04321670	ETH.MESH.04321681
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843
6/14/2006	Email Marie-Ange Damotte to Sungyoon Rha, et al. re TVT Laser Cut First Human Use - surgeon preference questionnaire	ETH.MESH.03274663	ETH.MESH.03274670
6/15/2006	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices	ETH.MESH.08164248	ETH.MESH.08164256
6/15/2006	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices	ETH.MESH.8164248	ETH.MESH.8164256
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347

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6/22/2006	Harel Gadot email re Laser Cut Mesh - Launch Strategy EMEA	ETH.MESH.998347	
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
6/23/2006	Price St. Hilaire email chain re Laser Cut Mesh - Launch Strategy EMEA	ETH.MESH.526484	
6/26/2006	Product Pointer: Gynecare TVT Tension-free Support for Incontinence -- available in laser cut mesh	ETH.MESH.00167119	ETH.MESH.00167119
6/27/2006	Kammerer email chain re Urgent *** French Standard on TVT & Meshes (Comments Required)	ETH.MESH.00585823	ETH.MESH.00585832
6/29/2006	Meier email re Minutes Hamburg Meeting June 2nd	ETH.MESH.00870465	ETH.MESH.00870476
7/14/2006	Trzewik email re Netzdiskussion	ETH.MESH.09671612	ETH.MESH.09671612
7/17/2006	TVT 20060717 Patient Brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003215	ETH.MESH.08003230
7/17/2006	TVT 20060717 TVT - The Choice to End Stress Urinary Incontinence	ETH.MESH.8003215	ETH.MESH.8003230
7/20/2006	Email Paula Evans to David Robinson et al. re TVT dataMcNelis, Linda	ETH.MESH.00311802	ETH.MESH.00311804
8/1/2006	Jürgen email re Fotos cadeavar lab	ETH.MESH.05454207	ETH.MESH.05454207
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482
8/28/2006	ICM Project Presentation	ETH.MESH.06001408	ETH.MESH.06001408
8/28/2006	lcm project	ETH.MESH.6001408	
8/29/2006	Second half photo presentation. ppt	ETH.MESH.00584527	ETH.MESH.00584527
9/27/2006	TVT016R6 Patient brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003231	ETH.MESH.08003246
10/4/2006	Mahar email chain re TVT LCM Early EU Feedback	ETH.MESH.00708571	ETH.MESH.00708576
10/4/2006	Hernandez J email chain re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
10/9/2006	Email Cheryl Bogardus to Dharini Amin re TVT 10 year anniversary/10 year data from Nillson	ETH.MESH.00524059	ETH.MESH.00524060
10/18/2006	Smith, Dan email chain re TVT Secur - TVT-Classic roping/sheath issues - failure to warn	ETH.MESH.1822361	ETH.MESH.1822636
12/18/2006	Patient advertisement for TVT	ETH.MESH.3460640	
12/19/2006	Smith, D email chain originating 12/15/2006 re TVT-S Cookbooks	ETH.MESH.519476	ETH.MESH.519481
12/20/2006	Robinson, D, email chain originating 12/15/2006 re TVT-S Cookbooks	ETH.MESH.1784428	ETH.MESH.1784435
12/22/2006	Emails re Contact at Lifescan who ran the BB King Campaign	ETH.MESH.8345895	
1/2/2007	TVT sales piece (TVTS004)	ETH.MESH.00161512	ETH.MESH.00161513
1/16/2007	"Confidential: History of TVT-O" by Axel Arnaud	ETH.MESH.3932909	ETH.MESH.3932911
1/23/2007	Qually 2006 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000322	ETHMESH.OHARA.00000327
1/25/2007	2005 Sales Rep Compensation Plan	ETH.MESH.5768705	ETH.MESH.5768712

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2/6/2007	Mahar email chain re hospital concern from medico-legal standpoint	ETH.MESH.00719198	ETH.MESH.00719209
2/6/2007	St. Hilaire email chain re OBGYN Department Members. Due to the potential serious implications . . .	ETH.MESH.00722339	ETH.MESH.00722349
2/7/2007	Robinson email chain re PLEASE DO NOT DISTRIBUTE THIE EMAIL!!! . . .broadcase bulletin re Dr. Levy	ETH.MESH.02316434	ETH.MESH.02316436
2/9/2007	Presentation: The (clinical) argument of lightweight mesh in abdominal surgery by Boris Batke	ETH.MESH.05475773	ETH.MESH.05475822
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
2/23/2007	Factors Related to Mesh Shrinkage: What do we know? A review of literature and internal studies	ETH.MESH.01782867	ETH.MESH.01782867
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair	ETH.MESH.2017152	
2/26/2007	Emails from David Robinson re modified version of TVT-O[TOT] procedure	ETH.MESH.00832937	ETH.MESH.00832939
3/20/2007	TVT-World-Wide Observational Registry for Long-Term Data Protocol 300-06-006 signed by David Robinson, Medical Director	ETH.MESH.539862	ETH.MESH.539898
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
5/4/2007	Timmer message re updated Mesh Shrinkage Discussion meeting w/attachments	HMESH_ETH_06509815	HMESH_ETH_06509817
5/11/2007	Email Price St. Hilaire to Dr Kavalier re AUA in Booth Activities	ETH.MESH.00136359	ETH.MESH.00136359
5/31/2007	Marketing Brochure - One day you have urine leakage. The next day you don't. End of Story.	ETH.MESH.08003263	ETH.MESH.08003278
6/1/2007	CDMA Eurpoe Meeting Urinary Incontinence Platform minutes June 1, 2007	ETH.MESH.03913651	ETH.MESH.03913665
6/1/2007	Trending analysis meeting presentation	ETH.MESH.14708810	ETH.MESH.14708848
6/5/2007	GYNECARE TVT SECUR Competitive Product Update 2007 by Dan Smith Dangerous Procedure/Tensioning	ETH.MESH.6861473	
7/6/2007	Engle email chain re How inert is polypropylene?	ETH.MESH.05447475	ETH.MESH.05447476
7/6/2007	Barbolt email chain re How inert is polypropylene	ETH.MESH.05447481	ETH.MESH.05447482
7/6/2007	Dr. Dieter Engle email chain re How inert is polypropylene?	ETH.MESH.5447475	
7/9/2007	Wohlert S email chain re How inert is polypropylene?	ETH.MESH.05588123	ETH.MESH.05588126
7/20/2007	Chomiak M email re Defining light weight mesh	ETH.MESH.05920616	ETH.MESH.05920617
7/20/2007	Emails between Paula Welland (UK Country Director), Paula Evans, and David Robinson re TVT data - underreporting of complications	ETH.MESH.311802	ETH.MESH.311804
7/20/2007	Emails re Defining light weight mesh	ETH.MESH.5920616	ETH.MESH.5920617
7/25/2007	Physician Brochure TVTS001RS - TVT SECUR System	ETH.MESH.00166287	ETH.MESH.00166292

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8/12/2007	Project plan Prosima M project lightning	ETH.MESH.03294572	ETH.MESH.03294581
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344
9/24/2007	EPC131 Revision A Neuchatel Prolift+M Product Specification	ETH.MESH.06214296	ETH.MESH.06214300
9/27/2007	Osman email chain re Wal-Mart Female Pelvic Health Poster Options	ETH.MESH.02114101	ETH.MESH.02114103
10/5/2007	Global Harms List Document for Review & Comment by Medical Affairs Personnel	ETH.MESH.06372356	ETH.MESH.06372363
10/5/2007	Global Harms List Document for Review & Comment by Medical Affairs Personnel	ETH.MESH.6372356	ETH.MESH.6372363
10/12/2007	Email Dr. Meng Chen to Carolyn Brennan	ETH.MESH.4090122	
11/1/2007	11.1.07 Internal Australian Meeting Re Secur	ETH.MESH.04126728	ETH.MESH.04126730
11/2/2007	Beath email chain re Meeting with the Australian Regulator to discuss TVT Secur performance	ETH.MESH.00312179	ETH.MESH.00312182
11/3/2007	Robinson email chain re URGENT: Meeting with the Australian Regulator ot discuss TVT Secur performance	ETH.MESH.00326865	ETH.MESH.00326870
11/12/2007	Aran Maree Email chain originating 11/08/2007 re Australia update and telephone call with Prof Frazer - "the IFU is fundamentally misleading . . ."	ETH.MESH.311792	ETH.MESH.311794
1/8/2008	Flores email chain re New complaint acknowledgement/request for info 10100062684	ETH.MESH.03509909	ETH.MESH.03509910
1/9/2008	Maree, A email chain re TGA Meeting	ETH.MESH.04127133	ETH.MESH.04127134
2/4/2008	Ullmann 2007 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000328	ETHMESH.OHARA.00000333
2/7/2008	Kahlsn H email chain re Conversion to Laset Cut TVT	ETH.MESH.16416002	ETH.MESH.16416004
2/8/2008	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson	ETH.MESH.08692660	ETH.MESH.08692667
2/8/2008	Nilsson Master Consulting Agreement	ETH.MESH.08692936	ETH.MESH.08692943
2/8/2008	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson	ETH.MESH.8692660	ETH.MESH.8692667
2/19/2008	Pelvic Floor Sumit	ETH.MESH.00057336	ETH.MESH.00057374
2/19/2008	Final Report Evaluation of Area Weight, PP Amount, Tensile Strength	ETH.MESH.10616895	ETH.MESH.10616956
2/21/2008	Vie email chain re TVTO vs. Boston Obtryx	ETH.MESH.07937979	ETH.MESH.07937981
2/22/2008	Executive Summary - Preliminary results of peri-operative and 3-month outcomes from a world-wide observational registry of tension-free vational tapes in with with SUI	ETH.MESH.01775242	ETH.MESH.01775257
2/29/2008	MiniMe R & O Final	ETH.MESH.858891	
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
3/3/2008	Harel Gadot email with attached diagram	ETH.MESH.1279975	

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3/3/2008	David Robinson email chain re Quality issue with a batch of gynemesh	ETH.MESH.328895	
3/4/2008	Gadot H email chain re Next step in SUI Sling	ETH.MESH.02293673	ETH.MESH.02293677
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945
3/14/2008	Risk Management Report (Legacy) for TVT and TVT-O	ETH.MESH.1265223	ETH.MESH.1265239
3/19/2008	Email Kyung Yu to Susie Chilcoat re Flynn preceptorships	ETH.MESH.03614158	ETH.MESH.03614158
3/19/2008	TVT 20080319 Gynecare TVT Family of Products Patients Brochure/Robin Osman	ETH.MESH.3458123	ETH.MESH.3458138
3/24/2008	Mahar K email chain re Project SCION Update & Next Steps	HMESH_ETH_0188106 0	HMESH_ETH_0188106 2
3/26/2008	Bonnie Blair - Find out how to stop uring leakage like Bonnie did	ETH.MESH.03458123	ETH.MESH.03458138
4/12/2008	Gauld email chain re Follow-up on US visit	ETH.MESH.03162936	ETH.MESH.03162938
4/15/2008	Trip Notes	ETH.MESH.02090196	ETH.MESH.02090209
4/15/2008	04/15/2008 Notes	ETH.MESH.03916716	ETH.MESH.03916727
4/15/2008	04/15/2008 Trip Notes	ETH.MESH.09909642	ETH.MESH.09909655
4/15/2008	04/15/2008 Trip Notes	ETH.MESH.15433760	ETH.MESH.15433773
4/15/2008	Notes	ETH.MESH.3916716	
4/16/2008	04/16/08 Notes	ETH.MESH.10003595	ETH.MESH.10003603
4/23/2008	Hernandez J email chain re Liege Trip Notes	ETH.MESH.03916715	ETH.MESH.03916715
4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
5/2/2008	Arnaud email re Mini TVT-O timeline	ETH.MESH.03914631	ETH.MESH.03914631
5/2/2008	Arnaud A email re clinical trial timeline - Mini TVT-O	ETH.MESH.03914631E	ETH.MESH.03914631E
5/5/2008	Arnaud email chain re sling business for SUI	ETH.MESH.03914629	ETH.MESH.03914630
5/6/2008	Form letter re TVTS4-Gynecare TVT Secur System	ETH.MESH.12939705	ETH.MESH.12939705
5/16/2008	Email Krystina Laguna to Price St. Hilaire re Copy Review TVT Complications	ETH.MESH.00345289	ETH.MESH.00345291
6/4/2008	Linton email re AUGS attendees	ETH.MESH.00057335	ETH.MESH.00057335
6/6/2008	Nilsson, et al. "Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence"	ETH.MESH.00355003	ETH.MESH.00355007
6/18/2008	Carl G. Nilsson Interview	ETH.MESH.04048515	ETH.MESH.04048520
6/30/2008	Lepley email chain re Urgent New complaint/request for information	ETH.MESH.03502981	ETH.MESH.0350298Y
7/29/2008	Kadackia R email chain re TVT LCM - launch delay due to OQ failure	ETH.MESH.09004550	ETH.MESH.09004553
8/14/2008	TVT Brochure "The Choice to End Stress Urinary Incontinence. Find out how to stop urine leakage like Bonnie did"	ETH.MESH.03459088	ETH.MESH.03459104
8/27/2008	Brennan email chain re TVT-S Mesh Torn Complaint Review for Wednesday morning Conf Call	ETH.MESH.09504558	ETH.MESH.09504559
8/27/2008	Scavona email chain re PQI TVT S	ETH.MESH.09504568	ETH.MESH.09504571

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9/5/2008	FOR IMMEDIATE RELEASE: New Study Offers More Than a Decade of Evidence for Minimally-Invasive Surgery to Treat Female Incontinence	ETH.MESH.03459211	ETH.MESH.03459212
9/24/2008	Email Melissa Day to Meng Chen, et al. re #10100078150	ETH.MESH.04099233	ETH.MESH.04099234
9/24/2008	Email Marcus Oldelehr to Brian Flynn re Flynn visit 10/23	ETH.MESH.19354118	ETH.MESH.19354119
9/25/2008	TVT sales piece	ETH.MESH.00164643	ETH.MESH.00164648
9/25/2008	Arnaud A email re TVT World registry	ETH.MESH.03914909	ETH.MESH.03914909
10/8/2008	Chaves email re MiniSling Abstract Overview & Nilsson Podcast	ETH.MESH.02123291	ETH.MESH.02123291
10/13/2008	Email from Jennifer Paine (WW Director, Regulatory Affairs) re FDA Public Health Notice on Surgical Mesh for POP and SUI - URGENT Product Defect Failure to Disclose Adverse Risks/Complications	ETH.MESH.329112	ETH.MESH.329113
10/14/2008	Voicemail from Kevin Mahar to EWH&U Sales & Marketing Organization re FDA PHN Product defect	ETH.MESH.66960	
10/20/2008	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	ETH.MESH.7937826	ETH.MESH.7937828
10/21/2008	FINAL FDA Notification About Use of Surgical Mesh to Treat POP and SUI Standby for Media/Analyst Inquiries	ETH.MESH.164023	ETH.MESH.164027
10/21/2008	Email from Renee Selman (WW President, Ethicon WH&U) to EWHU Team re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.2310653	ETH.MESH.2310657
11/1/2008	Piete Hinoul, MD Presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.1203957	
11/13/2008	Smith D memo: Things to consider as we assess next steps for a next generation sling	ETH.MESH.09911296	ETH.MESH.09911299
12/9/2008	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."	ETH.MESH.01673341	ETH.MESH.01673341
12/9/2008	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."	ETH.MESH.1673341	
12/10/2008	TVT 20081210 TVT - Treatment Options for Stress Urinary Incontinence	ETH.MESH.8003279	ETH.MESH.8003294
12/11/2008	Linda Linton email chain re TVT 11 Year E-blast Results (1st Round)	ETH.MESH.5183409	ETH.MESH.5183410
12/17/2008	Osman email chain . . . Unfortunately we can't print the new brochure . . . Regulatory rejected my Copy Review submission . . .	ETH.MESH.772228	ETH.MESH.772229

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12/17/2008	Osman email chain advise on next steps to get this brochure approved with the updated risk statement. . . .	ETH.MESH.772231	ETH.MESH.772232
12/18/2008	Universite De Liege and Ethicon Licensing Agreement	ETH.MESH.12002262	ETH.MESH.12002280
12/18/2008	Lisa email chain re TVT Patient Brochure Fair Balances/EPI Changes Change risks to brochure	ETH.MESH.339083	ETH.MESH.339084
12/19/2008	Email from Meng Chen to Sergio Gadaleta and Mark yale re #10100080654 and TVT IFUs	ETH.MESH.4092868	
1/1/2009	2009 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000340	ETHMESH.OHARA.00000346
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
1/7/2009	Hinoult P email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.03916905	ETH.MESH.03916913
1/7/2009	Total Petrochemicals Certificate N° 9	ETH.MESH.09955474	ETH.MESH.09955479
1/23/2009	Hinoult memo re meeting with Prof DeLeval and Prof Waltregny	ETH.MESH.04050265	ETH.MESH.04050265
1/25/2009	Letter re: Deleval	ETH.MESH.4050265	
1/26/2009	Issue Report	ETH.MESH.11985160	ETH.MESH.11985164
1/26/2009	Email from Joseph Scavona (Worldwide Quality) re TVT Complications Statement 2008 with attached draft slide of Complaint Reporting Statement with most significant reported TVT complications through December 2008	ETH.MESH.2122903	ETH.MESH.2122907
1/28/2009	Hinoult P email chain re TVT World AE Report	ETH.MESH.03208548	ETH.MESH.03208549
1/28/2009	Urquhart email re TVT World AE Report w/attachment	ETH.MESH.07181044	ETH.MESH.07181044
1/29/2009	Chen M email re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04093125	ETH.MESH.04093125
1/29/2009	Emails Bryan List to Meng Chen et al. re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04094863	ETH.MESH.04094864
2/2/2009	Meeting Agenda "AE and complication of the Isings	ETH.MESH.04081189	ETH.MESH.04081190
2/6/2009	Haby email re CR Approved 2009-98	ETH.MESH.00007091	ETH.MESH.00007091
2/23/2009	Zipfel R email chain re Ultrapro mesh info	ETH.MESH.07383730	ETH.MESH.07383731
2/25/2009	Email Jason Hernandez re Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday Mar 2nd	ETH.MESH.03208738	ETH.MESH.03208738
2/27/2009	Ciarrocca S email FW MiniMe discussion at the gboard meeting	ETH.MESH.09951746	ETH.MESH.09951793
3/2/2009	Hernandez J email chain re EWHU Board recommendation	ETH.MESH.00827376	ETH.MESH.00827379
3/4/2009	- Mini TVT-O Technical Assessment	ETH.MESH.06928076	ETH.MESH.06928077
3/5/2009	Interim report mesh explants pelvic floor repair	ETH.MESH.6636	
3/6/2009	Emails Scott Finley to Melissa Chaves re Fast Break Update	ETH.MESH.03966039	ETH.MESH.03966040

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3/6/2009	Ciarrocca email re Sling thoughts and next steps 11-13-08.doc	ETH.MESH.09951087	ETH.MESH.09951090
3/9/2009	Ullmann 2008 Performance and Developmnet Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000334	ETHMESH.OHARA.00000339
3/11/2009	Physican brochure/sales aid "Make Data and Safety your Choice"	ETH.MESH.00339053	ETH.MESH.00339057
3/11/2009	Hinoul P email re EJOGB-08-4159R1 - Minor Revision	ETH.MESH.00590896	ETH.MESH.00590897
3/17/2009	Ciarrocca S email re Updated Mini TVT-O Deck	ETH.MESH.01147115	ETH.MESH.01147115
3/19/2009	Mini TVT-O Stage Gate: SBT Discovery Initiation	ETH.MESH.01147116	ETH.MESH.01147116
3/19/2009	Mahar email chain re Credo debrief	ETH.MESH.06040657	ETH.MESH.06040658
3/20/2009	Letter Patricia Beach (Ethicon) to Dr. Douglas Grier re TVT World Registry	ETH.MESH.00407285	ETH.MESH.00407285
3/23/2009	Hinoul Protocol proposition - Modified TVT-O for the treatment of female stress incontinence: anatomical considerations	HMESH_ETH_02571221	HMESH_ETH_02571226
3/28/2009	Aaron Kirkemo email re My revised writeup of the DeLaval and Waltregny visit	ETH.MESH.1202101	
3/31/2009	Hinoul email re Mini TVTO	ETH.MESH.09952163	ETH.MESH.09952167
3/31/2009	Email Katrin Elbert to Piet Hinoul RE: MiniTVTO	ETH.MESH.09952168	ETH.MESH.09952169
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346227	ETH.MESH.00346227
4/8/2009	Hinoul email chain re registry for all!	ETH.MESH.00591127	ETH.MESH.00591128
4/8/2009	Hinoul email chain re Tensile Properties of POP Mesh	ETH.MESH.05238373	ETH.MESH.05238374
4/9/2009	Jones, S email re Tensile Properties of POP Mesh	ETH.MESH.05238382	ETH.MESH.05238384
4/20/2009	Chaves M email chain re CR Approved 2009-471 What's Left Behind Abbrevio	ETH.MESH.00057513	ETH.MESH.00057514
4/20/2009	Piet Hinoul letter re meeting with Prof deLeval and Prof Waltregny	ETH.MESH.01238552	ETH.MESH.01238553
4/22/2009	Email Piet Hinoul to Dan Smith re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238538	ETH.MESH.01238541
4/22/2009	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238551	ETH.MESH.01238551
4/22/2009	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.03917298	ETH.MESH.03917300
4/23/2009	Mini TVT-O Team Meeting	ETH.MESH.03643186	ETH.MESH.03643187
4/23/2009	Mini TVT-O Team Meeting	ETH.MESH.09956613	ETH.MESH.09956614
4/24/2009	Email Judi Gauld to Colin Urquhart re green journal	ETH.MESH.03259439	ETH.MESH.03259440
4/24/2009	Email Katrin Elbert to Anna-Caroline Cornec re Mesh strip for Mini-TVT O	ETH.MESH.09955374	ETH.MESH.09955374
4/24/2009	Elbert K email re Mesh strip for Mini-TVTO	ETH.MESH.17556513	ETH.MESH.17556513
4/28/2009	TVT-World-Wide Observational Registry for Long-Term Data	ETH.MESH.00533250	ETH.MESH.00533256
4/30/2009	Email Henri Decloux to Valerie Emperado re T-Con follow up	ETH.MESH.06928168	ETH.MESH.06928168
5/7/2009	Prolift+M Piet Hinoul, MD Pelvic Floor Meeting - Nederland, Utrecht, May 7, 2009	ETH.MESH.1264260	

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5/15/2009	Email Katrin Elbert to Henri Decloux re Last week's Medi-Line visit	ETH.MESH.09957926	ETH.MESH.09957927
5/20/2009	Email Stale Kvitle to Jean DeLeval, et al. re Mini Me follow up from our visit	ETH.MESH.15285672	ETH.MESH.15285672
5/26/2009	Brennan email chain re TVT Complications Statement 2008	ETH.MESH.02122903	ETH.MESH.02122905
5/26/2009	All Active CAPA's	ETH.MESH.02250914	ETH.MESH.02250945
5/26/2009	ASTM Designation: F 2097 - 08 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	ETH.MESH.06806078	ETH.MESH.06806092
6/3/2009	Chaves email re Fast Break Promotion Update	ETH.MESH.04314739	ETH.MESH.04314740
6/8/2009	Gynecare TVT Family of Products Tension-free Support for Incontinence Creative Brief Template	ETH.MESH.01184277	ETH.MESH.01184277
6/11/2009	Divilio Memo re The Use of Mesh in Hernia Repair	ETH.MESH.14442958	ETH.MESH.14442976
6/15/2009	Subramanian D email chain re Mini TVTO HE1 assessment	ETH.MESH.09960437	ETH.MESH.09960439
6/19/2009	Sunoco MSDS 2009	ETH.MESH.10630809	ETH.MESH.10630813
6/26/2009	Email Brian Flynn to Jonathan Fernandez re Contracted Pricing	ETH.MESH.08007248	ETH.MESH.08007249
6/29/2009	Hurley M email chain re SBT Meeting	ETH.MESH.07402878	ETH.MESH.07402879
7/1/2009	AdvaMed Code of Ethics on Interactions with Healthcare Professionals	ETH.MESH.00139845	ETH.MESH.00139867
7/15/2009	Email Brian Langen to Vincenza Zaddem re Plus-M payment for Mel Anhalt	ETH.MESH.10133116	ETH.MESH.10133116
7/16/2009	Robinson D email chain re TVT RR IFU Version 5 071409_T-3466	ETH.MESH.01239065	ETH.MESH.01239066
7/21/2009	Subramanian D email chain re EGS Mini TVTO	ETH.MESH.02322544	ETH.MESH.02322546
7/28/2009	Bobertz email chain re URGENT: Resin information request	ETH.MESH.06239100	ETH.MESH.06239108
7/30/2009	Email Takahito Hino to Patrice Napoda re TVT Japanese Package Insert	ETH.MESH.03656697	ETH.MESH.03656699
8/1/2009	2009 Field Visit Letter	ETH.MESH.10233144	ETH.MESH.10233148
8/7/2009	Email Severine Timoner Fortin to Valerie Emperado et al. re For Information - lot of TVT used for Deleval's tests	ETH.MESH.09951106	ETH.MESH.09951107
8/7/2009	Email Henri Decloux to Severine Timoner Fortin re Quote for sample production	ETH.MESH.09958050	ETH.MESH.09958051
8/8/2009	Hinoul email chain re For Information - lot of TVT used for Deleval's tests	ETH.MESH.09954485	ETH.MESH.09954486
8/17/2009	Prine email chain re TVT promotion Slam Dunk Winners	ETH.MESH.10227358	ETH.MESH.10227359
8/21/2009	Email David Waltregny to Piet Hinoul re TR: For Information - lot of TVT used for Deleval's tests	ETH.MESH.02596464	ETH.MESH.02596467
8/27/2009	Timoner Fortin email re Mini-O Raw material proposed by Suppliers for button aid	ETH.MESH.09955464	ETH.MESH.09955464

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9/11/2009	Mini TVT-O Stage Gate: Charter presentation	ETH.MESH.00758412	ETH.MESH.00758412
9/14/2009	Savidge S email chain re TVT RR IFU 090911b_T-3467	ETH.MESH.00592915	ETH.MESH.00592916
9/17/2009	Email Paul DeCosta to Thomas Divilio, et al. re: Mesh + Anti-proliferative agent	ETH.MESH.03722384	ETH.MESH.03722386
9/22/2009	Hinoul P email chain re TVTO mini IFU rewrite	ETH.MESH.00209295	ETH.MESH.00209299
9/25/2009	Savidge S email chain re TVTO Mini IFU questions	ETH.MESH.09952714	ETH.MESH.09952715
9/28/2009	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.03618587	ETH.MESH.03618596
9/29/2009	Communication Plan to close TVT World Registry	ETH.MESH.00533283	ETH.MESH.00533286
10/7/2009	Email Sandy Savidge to Katrin Elbert re TVTO mini IFU rewrite	ETH.MESH.00209965	ETH.MESH.00209968
10/19/2009	TVT-Exact IFU	ETH.MESH.211259	
10/21/2009	Email chain from Susan Lin re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.211263	
10/26/2009	Email from John Young to Aaron Kirkemo re IFU	ETH.MESH.10632650	
11/10/2009	Mini TVT-O Team Meeting	ETH.MESH.211038	ETH.MESH.211041
12/22/2009	Run on eg log.txt	ETH.MESH.3334244	
1/4/2010	Monthly Closed CAPA	ETH.MESH.03832685	ETH.MESH.03832692
1/5/2010	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA	ETH.MESH.00077727	ETH.MESH.00077732
1/8/2010	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 0) by Susan Lin to John Young	ETH.MESH.00340990	ETH.MESH.00340999
1/8/2010	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update by Susan Lin (Manager, Regulatory Affairs) to John Young (project leader for the TVT IFU update)	ETH.MESH.340990	ETH.MESH.340999
1/17/2010	Hinoul, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
1/21/2010	TVT Matketing email re 2010 Planning -- "Voice of the Customer" feedback	ETH.MESH.09234953	ETH.MESH.09234954
1/27/2010	TVT ad "Demand the most proven technology when selecting a mid-urethral sling... Make DATA and SAFETY YOUR CHOICE"	ETH.MESH.00349508	ETH.MESH.00349512
1/28/2010	Flores email chain re Continence Health Brand Team - TVT Feedback	ETH.MESH.09234951	ETH.MESH.09234952
2/6/2010	Peebles R email re Mesh slides for NTM	ETH.MESH.01805963	ETH.MESH.01805963
2/8/2010	Kirkemo A email chain re TVT Abbrevio and surgicenters	ETH.MESH.08581412	ETH.MESH.08581413
2/12/2010	2010 TVTS-029-10-2/12	ETH.MESH.02237103	ETH.MESH.02237104
2/16/2010	Toglia M email chain re Ethicon Women's Health and Urology National Training meeting - TVT	ETH.MESH.09235084	ETH.MESH.09235085
2/17/2010	Gynecare TVT Device Instructions for Use Revision Design Verification Memo by Kirkemo, Robinson and Hinoul	ETH.MESH.00340839	ETH.MESH.00340839

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2/17/2010	Holste email chain re PP vs PVDF or Pronova	HMESH_ETH_0022896 1	HMESH_ETH_0022897 3
2/19/2010	Beath C email re clinical data	ETH.MESH.02254087	ETH.MESH.02254087
2/24/2010	Gauld J email chain re TVT-Abbrevio	ETH.MESH.00350720	ETH.MESH.00350720
2/24/2010	Email Jonathan Fernandez to Carol Padgett re Dr. Alvina Driscoll	ETH.MESH.08014324	ETH.MESH.08014327
2/25/2010	Robinson D email chain re TVT Abbrevio	ETH.MESH.00073089	ETH.MESH.00073093
2/25/2010	Pruden G email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.00207012	ETH.MESH.00207015
2/25/2010	Robinson D email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.03923426	ETH.MESH.03923430
2/25/2010	Magalhaes I email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.06378084	ETH.MESH.06378089
2/26/2010	Physician brochure/sales aid	ETH.MESH.00659430	ETH.MESH.00659431
2/27/2010	Peebles R email re Rogliam participation in presentation	ETH.MESH.09214438	ETH.MESH.09214438
3/2/2010	Elbert K email chain re first draft equivalence Abbrevio	ETH.MESH.09956434	ETH.MESH.09956437
3/4/2010	EWHU 2009 Awards Ceremony	ETH.MESH.16263696	ETH.MESH.16263715
3/10/2010	Savidge S and Johnson L - biocompatibility statement	ETH.MESH.00074068	ETH.MESH.00074070
3/10/2010	Kirkemo A email re Scion PA commercial recommendation	ETH.MESH.00607406	ETH.MESH.00607410
3/10/2010	Kirkemo A email chain re Scion PA commercial recommendations	ETH.MESH.06927231	ETH.MESH.06927235
3/16/2010	Savidge S email chain re First draft equivalence Abbrevio	ETH.MESH.00351697	ETH.MESH.00351701
3/17/2010	Hibon email re TVT-Standard production stopped due to metallic particle on needles	ETH.MESH.13906093	ETH.MESH.13906093
3/17/2010	Ullman email chain re "Take Back Share" - Feb Update	ETH.MESH.19306944	ETH.MESH.19306946
3/19/2010	Bryan L email chain re EBM Sub-team meetings for EWHU	ETH.MESH.01201387	ETH.MESH.01201389
3/19/2010	Smith D email re Information regarding Scion	ETH.MESH.06927248	ETH.MESH.06927249
3/23/2010	Smith D email chain re Input to the one-pager to BR	ETH.MESH.00351439	ETH.MESH.00351441
3/23/2010	Kirkemo A email re Meeting with Bridget O Transformation nature of Scion delivery system	ETH.MESH.00600985	ETH.MESH.00600987
3/23/2010	Smith email chain re information regarding Scion	ETH.MESH.01216820	ETH.MESH.01216822
3/23/2010	Dormier E email chain re Meeting with Bridget - Transformation nature of Scion delivery system	ETH.MESH.01216831	ETH.MESH.01216833
3/24/2010	Iacobone email chain re Stability Testing	ETH.MESH.09932848	ETH.MESH.09932849
3/25/2010	Draft TVT Family strategic positioning overview presentation	ETH.MESH.00212665	ETH.MESH.00212665
3/25/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate EWHU Board presentation	ETH.MESH.01538120	ETH.MESH.01538120
3/25/2010	Zaddem V email chain re Your input on 30 in 3 and Speed to launch	ETH.MESH.02013947	ETH.MESH.02013948

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4/6/2010	Elbert K email chain re CO-0022344 for your review; Target Approval 4-12-2010 12:00:00 AM EDT	ETH.MESH.10632641	ETH.MESH.10632644
4/6/2010	Elbert K email chain re CO-0022344 for your review, Target Approval 04-12-2010	ETH.MESH.11205022	ETH.MESH.11205027
4/6/2010	Taggart D email chain re CO-002344 for your review: Target Approval 04-12-2010 12:00 AM EDT	ETH.MESH.14819286	ETH.MESH.14819290
4/7/2010	Robinson D email re Please hold: database study vendor selection	ETH.MESH.00602025	ETH.MESH.00602027
4/9/2010	NCR Summary Report NCR10-01914	ETH.MESH.05620358	ETH.MESH.05620362
4/12/2010	Extend the control of your hand 2010 TVTE-187-10-4/12 sales aid	ETH.MESH.02235661	ETH.MESH.02235664
4/14/2010	TVT Retropublic Refresh	ETH.MESH.00223801	ETH.MESH.00223828
4/15/2010	Project Mini TVT-O Team: Gynecare TVT Abbrevio Continence System	ETH.MESH.09922406	ETH.MESH.09922406
4/19/2010	Waltregny D email chain re Your Submission	ETH.MESH.00574783	ETH.MESH.00574783
4/19/2010	Wess A email chain re de leval paper	ETH.MESH.03627114	ETH.MESH.03627114
4/19/2010	Minutes for Project Mini TVTO Design Outputs Design Review	ETH.MESH.16433747	ETH.MESH.16433756
4/28/2010	TVT Family of Products Co-positioning EWHU Board Pre-Reading	ETH.MESH.00750880	ETH.MESH.00750881
5/12/2010	TVT-O IFU (05/12/2012-present)	ETH.MESH.02340902	ETH.MESH.02340973
5/14/2010	Kirkemo A email chain re Review of Scion 2 year data	ETH.MESH.01252509	ETH.MESH.01252512
5/14/2010	Biocompatibility Assessment of Medi-Line Use of Down Corning 200 Fluid (100 cst) In Gynecare TVT Products	ETH.MESH.01320395	ETH.MESH.01320519
5/14/2010	Barendse email re TVT Exact Meeting Follow-up	ETH.MESH.10232709	ETH.MESH.10232709
5/18/2010	TVT Abbrevio Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
5/18/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate PLT	ETH.MESH.09183969	ETH.MESH.09184024
5/18/2010	TVT Abbrevio Launch Planning Stage Gate PLT	ETH.MESH.09294125	ETH.MESH.09294125
5/18/2010	Stagegate Presentation - slide 41 - projected COGS, AS...	ETH.MESH.09936426	ETH.MESH.09936427
5/28/2010	Consulting Agreement Requisition Form between Brian J. Flynn and Ethicon	ETH.MESH.00493332	ETH.MESH.00493343
6/11/2010	Jones email chain re Prosima Preceptorships	ETH.MESH.08023341	ETH.MESH.08023342
6/14/2010	2011 EWHU Business Planning presentation	ETH.MESH.03642659	ETH.MESH.03642659
6/16/2010	Hart email chain re Investigator-Initiated Studies Policy	ETH.MESH.05347751	ETH.MESH.05347769
6/16/2010	NCR Summary Report NCR10-02107	ETH.MESH.05620371	ETH.MESH.05620382
6/16/2010	NCR Summary Report NCR10-02199	ETH.MESH.05620383	ETH.MESH.05620388
6/29/2010	Lisa B email re TVT Abbrevio claims support	ETH.MESH.00346157	ETH.MESH.00346157
6/29/2010	Smith email re New TVT +M mesh	ETH.MESH.04987190	ETH.MESH.04987191
6/30/2010	Landgrebe S email chain re matrix-Cohera	ETH.MESH.06869163	ETH.MESH.06869166
7/1/2010	TVT-Abbrevio FDA communication and 510k	ETH.MESH.00343129	ETH.MESH.00343225

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7/1/2010	TVT Abbrevio 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
7/5/2010	MD&D Complaint Form - Complaint ID CC1007005	ETH.MESH.03497846	ETH.MESH.03497847
7/5/2010	Email Kathie Chen to Darlene Jane Kyle, et al. re Product Complaint CC1007005-Taiwan	ETH.MESH.13204508	ETH.MESH.13204521
7/6/2010	Beath C email chain re 510K clearance	ETH.MESH.02254165	ETH.MESH.02254165
7/7/2010	Peter K email re TOPA timing - draft for review and input	ETH.MESH.02178872	ETH.MESH.02178873
7/12/2010	Poulot email chain re BHR EWHU 3413118, 398077, 3405428	ETH.MESH.13896042	ETH.MESH.13896043
7/13/2010	Samuel S email re Key Steps Flashcare Clarification	ETH.MESH.01675805	ETH.MESH.01675806
7/15/2010	Email Vincenza Zaddem to Alyssa Kilayko re obt muscle thickness values	ETH.MESH.02019485	ETH.MESH.02019485
8/2/2010	Email Darlene Jane Kyle to Kathie Chen re Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)	ETH.MESH.13206130	ETH.MESH.13206134
8/3/2010	Complaint Number: PI1-EWT0A6	ETH.MESH.14908783	ETH.MESH.14908783
8/3/2010	Complaint Number: PI1-F8GCTO	ETH.MESH.14967283	ETH.MESH.14967283
8/5/2010	Amin D email chain re Gynecare TVT Abbrevio advisory board members	ETH.MESH.09164480	ETH.MESH.09164481
8/6/2010	Clinical Evaluation Report, Robinson, Gynecare TVT Obturator System Tension-free Support for Incontinence	ETH.MESH.07219684	ETH.MESH.07219723
8/8/2010	Pagel K email re Prof Ed deck (draft 2 still) w/o video	ETH.MESH.01201955	ETH.MESH.01201956
8/11/2010	Hinoul P email re CER Abbrevio	ETH.MESH.00826026	ETH.MESH.00826027
8/11/2010	Hinoul Clinical Expert Report	ETH.MESH.00826028	ETH.MESH.00826045
8/16/2010	Email Brian Flynn to Jonathan Fernandez re permission	ETH.MESH.03432766	ETH.MESH.03432766
8/17/2010	Hinoul Clinical Expert Report	ETH.MESH.01795909	ETH.MESH.01795929
8/17/2010	MD&D Resolution Form	ETH.MESH.03497878	ETH.MESH.03497878
8/17/2010	Email Celine Heramza to Carolyn Brennan re Assignment "Product evaluation" has been closed for Issue #:10100122655	ETH.MESH.13210344	ETH.MESH.13210346
8/17/2010	Jaccard email chain re Particles in production w/attachment	ETH.MESH.13907355	ETH.MESH.13907355
8/17/2010	Clinical Expert Report Gynecare TVT Abbrevio	ETH.MESH.1795909	
8/24/2010	Email from Carlos E. Lugo-Ponce to Darlene Jane Kyle et al re Product Complaint CC1007005-Taiwan	ETH.MESH.01745568	ETH.MESH.01745572
8/30/2010	Wise E email chain re DoC for TVT Abbrevio	ETH.MESH.03654499	ETH.MESH.03654499
9/1/2010	Email Shalot Armstrong to Carlos E Lugo-Ponce re Product Complaint CC1007005-Taiwan	ETH.MESH.04101817	ETH.MESH.04101822
9/1/2010	Briceño Memo to DHF0000978 - TOPA re Preliminary Risk Analysis for TVT-O PA	ETH.MESH.06015227	ETH.MESH.06015229
9/2/2010	EWHU Incontinence EWHU Board Meeting Presentation - TVTO version 3	ETH.MESH.00751159	ETH.MESH.00751159
9/10/2010	TVT-ABBREVO IFU 20100910	ETH.MESH.02341203	ETH.MESH.02341267
9/10/2010	TVTO-PA Clinical Strategy - Final Version	ETH.MESH.06923868	ETH.MESH.06923871

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9/13/2010	Meier CER Mesh Erosions	ETH.MESH.03721328	ETH.MESH.03721449
9/13/2010	Customer Requirements Specification (CRS) for Project TVT-O PA Revision History	ETH.MESH.06917699	ETH.MESH.06917704
9/15/2010	DH0263-0278 DH0269: TVT (Tension Free Vaginal Tape) Factbook	ETH.MESH.1317508	ETH.MESH.1317613
9/16/2010	Interim (28 day) Report, PSE Accession No. 10-0126, Project No. 11730	HMESH_ETH_02041604	HMESH_ETH_02041626
9/21/2010	Paradise email chain re GYNecare TVT Obturator Sales: Feedback needed	ETH.MESH.09133724	ETH.MESH.09133725
9/25/2010	Hinoult Presentation - An anatomic comparison of the traditional TVT-O versus a modified TVT-O procedure	ETH.MESH.04933406	ETH.MESH.04933406
9/25/2010	Abbrevio Ad Board Notes	ETH.MESH.09218059	ETH.MESH.09218064
9/30/2010	Mahar K email chain re Key docs at AUGS	ETH.MESH.08344659	ETH.MESH.08344659
9/30/2010	Peebles R email re Transcription	ETH.MESH.09218058	ETH.MESH.09218058
10/1/2010	Flax C email chain re TVT Abbrevio material	ETH.MESH.00796051	ETH.MESH.00796052
10/4/2010	Elbert K email chain re hold for Abbrevio Lessons Learned	ETH.MESH.09970762	ETH.MESH.09970762
10/5/2010	Brennan email chain re 10100124625 etc. - MEMO re TVT-O particles	ETH.MESH.04101014	ETH.MESH.04101015
10/5/2010	Smith email chain re Need help on Sample Size for Stability Dimensions	ETH.MESH.07356789	ETH.MESH.07356790
10/6/2010	Hinoult P email chain re Abbrevio use in Leige	ETH.MESH.02599695	ETH.MESH.02599695
10/11/2010	Destefano C email re CR Approved: TVTA-474-10-10_12 Gynecare TVT Abbrevio Clinical Data Review Flashcard	ETH.MESH.09161482	ETH.MESH.09161484
10/11/2010	Christine Destefano email re Approved TVTAA-474-10-10_12 Gynecare TVT Abbrevio Clinical Data Review Flashcard	ETH.MESH.9161482	ETH.MESH.9161484
10/12/2010	The efficacy she needs with less mesh	ETH.MESH.02231537	ETH.MESH.02231538
10/18/2010	Linn email chain re Exception request for Abbrevio Professional education deck	ETH.MESH.00354234	ETH.MESH.00354234
10/25/2010	Zipfel R email re Anhalt - NY Times article - Trial of Synthetic Mesh in Pelvic Surgery Ends Early	ETH.MESH.00427910	ETH.MESH.00427910
10/27/2010	Revision Hx FM-0000167 Revision 4	ETH.MESH.03652924	ETH.MESH.03652955
10/28/2010	Hinoult P email chain re Dr. Waltregny contribution during Abbrevio training	ETH.MESH.02599885	ETH.MESH.02599886
11/2/2010	Process Qualification of FSMK0238 Revision 1	ETH.MESH.15257129	ETH.MESH.15257155
11/5/2010	Cecchini email chain re Ethicon DVD	ETH.MESH.11336648	ETH.MESH.11336648
11/8/2010	Innovation Council agenda	ETH.MESH.10132609	ETH.MESH.10132620
11/8/2010	TVT 20101108 Stop Coping Start Living . . .	ETH.MESH.6087471	ETH.MESH.6087472
11/9/2010	Krause email chain re Ethicon DVD	ETH.MESH.08516133	ETH.MESH.08516134
11/24/2010	TVT Abbrevio Dublin Meeting brochure	ETH.MESH.02596794	ETH.MESH.02596794
11/30/2010	Robinson D email chain re Organization of EWHU Workshops	ETH.MESH.03259032	ETH.MESH.03259035

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12/6/2010	Kirkemo A Dear Dr. unsolicited request for information letter	ETH.MESH.01226442	ETH.MESH.01226445
12/6/2010	Kirkemo A email re Your unsolicited request for medical information - MIR	ETH.MESH.01265511	ETH.MESH.01265511
12/6/2010	Patel email chain re TVT+M mesh question	ETH.MESH.09983201	ETH.MESH.09983201
12/9/2010	Henderson M email chain re Q4 Spend	ETH.MESH.05791132	ETH.MESH.05791133
12/9/2010	TVTR-566-10-11/12 Physician brochure - Gynecare TVT	ETH.MESH.06087513	ETH.MESH.06087514
12/9/2010	Irvin, M 12/08/2010 Post Call Notes	ETH.MESH.08041930	ETH.MESH.08041931
12/9/2010	Greg Prine email chain re New Gynecare TVT Abbrevio sales literature and DVD now available.	ETH.MESH.10237693	
12/9/2010	Vellucci email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	HMESH_ETH_07956799	HMESH_ETH_07956800
12/13/2010	MOntly Complaint Review November 2010	ETH.MESH.00540449	ETH.MESH.00540449
1/1/2011	Briefing Documents - Operation Abbrevio	ETH.MESH.11434367	ETH.MESH.11434379
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
1/16/2011	Presentation by Boris Batke (Associate Director, R&D): Chronic Pain - Prevention/future - Bioengineer's point of view	ETH.MESH.5916450	
1/18/2011	PA Consulting Group Mesh Erosion Interview Memo	ETH.MESH.07192412	ETH.MESH.07192414
1/20/2011	Physician Survey Results presentation	ETH.MESH.00791766	ETH.MESH.007911766
1/21/2011			
	RDLT 3 month post-launch close out - slide 12 Lessons ...	ETH.MESH.09936503	ETH.MESH.09936503
1/26/2011	Patient Brochure - Treatment Options for Stress Urinary Incontinence -- stop coping. start living.	ETH.MESH.08003303	ETH.MESH.08003318
2/1/2011	Master Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05276184	ETH.MESH.05276194
2/7/2011	TVT-039-11-1/13 Patient brochure - stop coping. start living	ETH.MESH.08003295	ETH.MESH.08003302
2/8/2011	Dang email chain re K103727 - please advise	ETH.MESH.06016054	ETH.MESH.06016055
2/8/2011	ETH.MESH.10630803.Braskem msds 2011	ETH.MESH.10630803	ETH.MESH.10630808
2/10/2011	Beath email chain re Ethicon Mesh DVD - FDA Request Follow Up	ETH.MESH.05573254	ETH.MESH.05573254
2/11/2011	Letter from Pollard to Lin, date-stamped K103727 Trade Name: GYNECARE TVTO-PA Continence System	ETH.MESH.00206974	ETH.MESH.00206981
2/11/2011	Email Jennifer Haby to Sheelu Samuel re CR Aprvd: TVTA-088-11_TVT ABBREVO Prof Ed Slides Revised	ETH.MESH.03419391	ETH.MESH.03419391
2/13/2011	TVTA-083-11-2/13 - 1 Year RCT Trial Annotated Guide	ETH.MESH.02235375	ETH.MESH.02235387
2/14/2011	Roji A email re VOTE team 2010 1:1 calls	ETH.MESH.03981288	ETH.MESH.03981290
2/15/2011	FDA Review of PFR and SUI Mesh Products - Changing Regulatory Environment and Potential Impact on Ethicon Pipeline - presentation	ETH.MESH.05604390	ETH.MESH.05604399
2/16/2011			
	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855

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2/19/2011	Mesh Processing Meshes Fabricated from Dissimilar Materials - Summary Document - Draft	ETH.MESH.22140265	ETH.MESH.22140266
2/21/2011	Lewis 2010 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000347	ETHMESH.OHARA.00000353
2/22/2011	Voelker email chain re Approval of EMQD10: ECO354770	ETH.MESH.06165103	ETH.MESH.06165105
2/23/2011	Internal Notes - Memo	ETH.MESH.01216125	ETH.MESH.01216150
2/23/2011	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock, Rev. 5	ETH.MESH.02219202	ETH.MESH.02219210
2/23/2011	Smith email chain re PC 10-029	ETH.MESH.15257127	ETH.MESH.15257128
2/24/2011	Email Jonathan Fernandez to Brian Flynn, et al. re Flynn contracts	ETH.MESH.08005908	ETH.MESH.08005909
2/28/2011	Gauld email re Here is the copy of FDA's letter (please do not forward)	ETH.MESH.00206973	ETH.MESH.00206973
2/28/2011	Kevin Frost email chain re SGS Fellows Symposium	ETH.MESH.08170224	ETH.MESH.08170232
3/1/2011	Presentation: ETHICON Polypropylene Mesh Technology by Boris Batke, Associate Director R&D	ETH.MESH.5479717	
3/2/2011	Hinoul email re Laser cut mesh tape	ETH.MESH.00576844	ETH.MESH.00576845
3/2/2011	Project TVTO PA SBT Stage Gate Chater Update Presentation	ETH.MESH.02238117	ETH.MESH.02238117
3/7/2011	Garbarino S email chain re 2011 VOTE Team Conf Call - VOTE Team Questions	ETH.MESH.03898831	ETH.MESH.03898834
3/7/2011	Benjamin email re FDA ltt re 510k	ETH.MESH.06015196	ETH.MESH.06015196
3/8/2011	Papas N email chain re AUGS abstract	ETH.MESH.00575160	ETH.MESH.00575161
3/9/2011	Kirkemo A email re Abbrevio - initial holding force - MIR	ETH.MESH.02592466	ETH.MESH.02592466
3/9/2011	Kirkemo A Dear Dr. unsoliciated request for information letter	ETH.MESH.02592467	ETH.MESH.02592470
3/9/2011	Papas N email chain re AUGS Abstract	ETH.MESH.16434349	ETH.MESH.16434352
3/11/2011	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.05276086	ETH.MESH.05276097
3/14/2011	Email Alyson Wess to Georgia Long, et al. re Incontinence PMT: 3/3 meeting notes	ETH.MESH.05163323	ETH.MESH.05163325
3/15/2011	Elaine Wise Product Monograph	ETH.MESH.12627553	ETH.MESH.12627577
3/15/2011	Kaminski email chain re Prosima Preparation	ETH.MESH.18846146	ETH.MESH.18846147
3/16/2011	Volpe email chain re TVT+M for Peter	ETH.MESH.05403773	ETH.MESH.05403773
3/17/2011	WEss A email chain re Incontinence PMT: 3/3 meeting notes	ETH.MESH.04062405	ETH.MESH.04062407
3/28/2011	Proposed contents for TVTOPA Pre-IDE Meeting with FDA	ETH.MESH.06015198	ETH.MESH.06015198
3/29/2011	Frost K email re PF Summit Presentations	ETH.MESH.08969368	ETH.MESH.08969368
3/31/2011	Hinoul email chain re Workshop on Vaginal Tapes	ETH.MESH.07236294	ETH.MESH.07236295
3/31/2011	EWHU: Faculty Training - Sonoma CA Agenda	ETH.MESH.10818814	ETH.MESH.10818814
3/31/2011	Phillips, K email re Lack of quality engineering support for Prosima+M	ETH.MESH.11790162	ETH.MESH.11790162

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3/31/2011	Letter by Piet Hinoul, Medical Affairs Director, re Workshop on Vaginal Tapes	ETH.MESH.7236294	ETH.MESH.7236297
4/1/2011	Ethicon 2011 Incontinence & Pelvic Floor Summit agenda	ETH.MESH.10818815	ETH.MESH.10818816
4/1/2011	Gerin-Roze email chain re TVT-S Lot related to NCR11-01867	ETH.MESH.11770891	ETH.MESH.11770892
4/4/2011	DRAFT - PA Strategy Review presentation	ETH.MESH.01201047	ETH.MESH.01201068
4/6/2011	Hoffman S email chain re 6 weeks into Abbrevo Launch	ETH.MESH.10224489	ETH.MESH.10224490
4/7/2011	Ethicon 360 Gynecare TVT Abbrevo uses a refined obturator procedure so that you can use less mesh with confidence	ETH.MESH.05572669	ETH.MESH.05572669
4/10/2011	Feinberg email chain re TVTO PA full team meeting minutes, Thursday April 7th	ETH.MESH.09982887	ETH.MESH.09982888
4/19/2011	Monthly Complaint Review	ETH.MESH.00540629	ETH.MESH.00540629
4/21/2011	Frost K email re 2011 Incontinence & Pelvic floor REcap	ETH.MESH.10818812	ETH.MESH.10818813
4/22/2011	TVTOPAC Cadaver Lab Report	ETH.MESH.02218436	ETH.MESH.02218439
4/25/2011	Briceno J email re 1st Post PRA review TVT Abbrevo	ETH.MESH.01216122	ETH.MESH.01216122
4/25/2011	Briceño J Memo re TVT Abbrevo - Risk Assessment Review	ETH.MESH.01216123	ETH.MESH.01216124
4/26/2011	Smith email re TVT+M mesh	ETH.MESH.06165243	ETH.MESH.06165243
4/29/2011	Holloway email chain re Removal of TVT-O system due to severe neuropathic leg pain - MIR	ETH.MESH.13284086	ETH.MESH.13284088
5/12/2011	Decker R email re Abbrevo letter	ETH.MESH.07954867	ETH.MESH.07954867
5/13/2011	Email Laura Hutto to Brian Luscombe re Flynn	ETH.MESH.05822684	ETH.MESH.05822693
5/13/2011	Decker R email chain re Abbrevo letter	ETH.MESH.07954703	ETH.MESH.07954705
5/16/2011	US EWHU Executive Performance Review Presentation	ETH.MESH.03643726	ETH.MESH.03643726
5/16/2011	US EWHU Executive Performance Review presentation	ETH.MESH.036443726	ETH.MESH.036443726
5/16/2011	Ona Bernal email chain re Week 1: TVT Abbrevo Eval	ETH.MESH.11445930	
5/18/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.02589032	ETH.MESH.02589079
5/18/2011	Berman, Robinson, Wang, Rhodes - Report - Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.03750903	ETH.MESH.03750950
5/18/2011	Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.2589032	ETH.MESH.2589079
5/26/2011	Project NEO - DHF0000979 Medical Affairs NEO DRM Rationales	ETH.MESH.02030340	ETH.MESH.02030356
5/30/2011	Spreadsheet listing microporous, medium and macroporous meshes	ETH.MESH.5479535	
6/2/2011	Holloway email chain re TVT-O medial and lateral leg pain - MIR CHATS # 10100143432	ETH.MESH.13213760	ETH.MESH.13213766
6/6/2011	CA to audit abbrevo(1)	ETH.MESH.08776497	ETH.MESH.08776521

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6/7/2011	Jones S email re conference call on converting an outside in user to Abbrevio	ETH.MESH.17556602	ETH.MESH.17556603
6/8/2011	O'Connell email chain re Articles of Mesh Properties	ETH.MESH.00185184	ETH.MESH.00185184
6/22/2011	Berman, Robinson, Wang, Rhodes Investigating Mesh Erosion in Pelvic Floor Repair presentation	ETH.MESH.07192929	ETH.MESH.07192977
6/30/2011	Affeld, T email chain re PS vs +M	ETH.MESH.07903682	ETH.MESH.07903683
7/6/2011	Miller D email chain re Prolift professional education	ETH.MESH.05337217	ETH.MESH.05337220
7/6/2011	Luscombe B email chain re request from Miller re lecture material	ETH.MESH.05337225	ETH.MESH.05337228
7/6/2011	Dennis Miller, MD email chain re pore classification	ETH.MESH.5337217	
7/12/2011	Scion SBT Presentation - slide 9 - Abbrevio COGS, ASP, GP...	ETH.MESH.00996929	ETH.MESH.00996929
7/12/2011	slide 19 Abbrevio COGS, ASP. GP	ETH.MESH.06921562	ETH.MESH.06921562
7/12/2011	Scion SBT Presentation - slide 9 - Abbrevio COGS, ASP, GP...	ETH.MESH.0996929	ETH.MESH.0996929
7/13/2011	Email Bridget Ross (WW President, EWH&U) re FDA Health Notification	ETH.MESH.02253078	ETH.MESH.02253079
7/13/2011	Email from Bridget A. Ross (WW President, EWH&U) re FDA Health Notification Product Defect Mesh-related complications not seen in traditional repairs	ETH.MESH.2253078	ETH.MESH.2253079
7/29/2011	Email Vijay Madikonda re BSI Technical File Audit - July 28-29, 2011	ETH.MESH.00301367	ETH.MESH.00301369
8/4/2011	Lin Itt FDA re K103727 Gynecare TVTO-PA Continence System - Request for Withdrawal of 510k	ETH.MESH.07455424	ETH.MESH.07455425
8/4/2011	Gynecare RVTO-OA - Request for Withdrawal of 510k	ETH.MESH.10635251	ETH.MESH.10635515
8/8/2011	TOPA withdraw confirmation	ETH.MESH.20006789	ETH.MESH.20006791
8/16/2011	Draft - Matrix 1,2 -- Tissue Bulking Material, Methods, and Devices (external bulking)	ETH.MESH.22140235	ETH.MESH.22140238
8/26/2011	Karl J email chain re Braskem. . . A Little History	ETH.MESH.06261965	ETH.MESH.06261967
8/30/2011	Samuel S email re Mesh Data	ETH.MESH.11175841	ETH.MESH.11175842
10/6/2011	Email Libby Lewis to Mary Byerly re Western Region Needs	ETH.MESH.11445493	ETH.MESH.11445494
10/12/2011	Clinical Registry Report - Protocol Number: 300-06-006	ETH.MESH.02877814	ETH.MESH.02881493
11/1/2011	Smith Memo re Scion SIS development history summary; VOC, Human factors, Cadaver labs, Internal R&D	ETH.MESH.06857127	ETH.MESH.06857132
11/9/2011	AAGL Las Vegas meeting brochure	ETH.MESH.00107688	ETH.MESH.00107688
11/16/2011	Draper S email re Initial Letter to Manufacturer MHRA Re. . .	ETH.MESH.03488556	ETH.MESH.03488564
12/2/2011	Henderson email - Gynecologic and Obstetric Investigation (1983) Abstract	ETH.MESH.15354959	ETH.MESH.15354959

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12/6/2011	PLT 12 month post-launch close out PPT - slide 17 Executive Summary.	ETH.MESH.09977270	ETH.MESH.09977271
12/10/2011	London Memo to Parisi and Mahar re VOC on new laser Cut TVT Mesh	ETH.MESH.1809082	ETH.MESH.1809083
1/16/2012	Draft - Uniform three dimensional tissue scaffold of absorbable and non-absorbable materials	ETH.MESH.22140231	ETH.MESH.22140234
2/1/2012	Postmarket Surveillance Plan: PS120095 GYNECARE TVT Secure System KO52401	ETH.MESH.04474763	ETH.MESH.04474770
2/1/2012	Grier Consulting Agreement Requisition Form	ETH.MESH.09155883	ETH.MESH.09155895
2/1/2012	Consulting Agreement Requisition Form - Part I Ethicon and Melvyn A. Anhalt	ETH.MESH.09155909	ETH.MESH.09155920
2/16/2012	PowerPoint - EWHU Incontinence 2012 Pipeline Refresh	ETH.MESH.03644217	ETH.MESH.03644217
2/24/2012	Lapinskas, I, email chain originating re Discussion of 3.5 mil Prolene production	ETH.MESH.07730291	ETH.MESH.07730295
2/28/2012	Hinoul P email chain re CER Abbrevio CER	ETH.MESH.07226914	ETH.MESH.07226963
3/1/2012	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation	ETH.MESH.04015102	ETH.MESH.04015104
3/1/2012	Vellucci, L email chain re Polypropylene Mesh	ETH.MESH.07226377	ETH.MESH.07226379
3/1/2012	Laura Vellucci email chain originating January 26, 2012 re Polypropylene mesh - study of 100 explants	ETH.MESH.7226377	ETH.MESH.7226379
3/5/2012	Savidge email chain re TVT-O mesh weight	ETH.MESH.07502642	ETH.MESH.07502645
3/6/2012	Response to MHRA inquiry regarding inertness of polypropylene mesh	ETH.MESH.07455220	ETH.MESH.07455221
3/7/2012	Issues Report Run Between 10/01/2010 and 02/14/2012	ETH.MESH.02652179	ETH.MESH.02652317
3/11/2012	PV Minutes of TAM meeting	ETH.MESH.13886781	ETH.MESH.13886782
3/12/2012	Hinoul P email chain re Patient complication in Wichita, KS	ETH.MESH.05998775	ETH.MESH.05998778
3/12/2012	Savidge, et al response to email from Huntington re 'Clave' publication	ETH.MESH.07205369	ETH.MESH.07205370
3/14/2012	Independent MD&D Sector Audit by QualityHub, Inc. Pore size	ETH.MESH.07724068	ETH.MESH.07724080
3/15/2012	Innovations in Mesh Development by Boris Batke	ETH.MESH.04037600	ETH.MESH.04037600
3/25/2012	The efficacy she needs with less mesh	ETH.MESH.13681529	ETH.MESH.13681532
4/2/2012	DeLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941623	ETH.MESH.03941623
4/2/2012	Hinoul P email chain re Prof de Leval - TVT Abbrevio	ETH.MESH.04938298	ETH.MESH.04938299
4/2/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998811	ETH.MESH.05998812
4/2/2012	Barnes C email chain re Ethicon Gynecare Innovations Event	ETH.MESH.17556496	ETH.MESH.17556497
4/3/2012	deLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941617	ETH.MESH.03941618
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.03941621	ETH.MESH.03941622
4/3/2012	Hinour P email chain re Alerte TVT Abbrevio	ETH.MESH.05998803	ETH.MESH.05998804
4/3/2012	Hinour P email chain re Alerte TVT Abbrevio	ETH.MESH.05998805	ETH.MESH.05998806
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998807	ETH.MESH.05998808

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4/3/2012	Peebles R email chain re Alerte TVT Abbrevio	ETH.MESH.09227440	ETH.MESH.09227441
4/3/2012	Beccia N email chain re Alerte TVT Abbrevio	ETH.MESH.10051284	ETH.MESH.10051286
4/3/2012	Pitts L email chain re Alerte TVT Abbrevio	ETH.MESH.10051331	ETH.MESH.10051333
4/3/2012	Prine G email chain re Alerte TVT Abbrevio	ETH.MESH.12730858	ETH.MESH.12730860
4/3/2012	Barnes C email chain re ACT REQ: Urgent quick need request	ETH.MESH.17556511	ETH.MESH.17556511
4/4/2012	Steele J email chain re Alerte TVT Abbrevio	ETH.MESH.03985932	ETH.MESH.03985934
4/4/2012	Langen B email re SMII Welcome Letter	ETH.MESH.17556512	ETH.MESH.17556512
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998816	ETH.MESH.05998818
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998819	ETH.MESH.05998820
4/5/2012	Luscombe B emial re Brand Team for Inc POP	ETH.MESH.17556486	ETH.MESH.17556487
4/11/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998821	ETH.MESH.05998823
4/12/2012	Ethicon Gynecare Innovations flyer	ETH.MESH.17556498	ETH.MESH.17556498
4/27/2012	Hinoul P email chain re slings at surgery center	ETH.MESH.05572526	ETH.MESH.05572528
4/27/2012	Barnes C email chain re Ty Erickson Adobe Connect's with Abbrevio	ETH.MESH.17556538	ETH.MESH.17556539
4/30/2012	Peebles, R email chain re Alerte TVT Abbrevio	ETH.MESH.09227438	ETH.MESH.09227439
5/1/2012	Pramudji fax re Contract	ETH.MESH.08066401	ETH.MESH.08066414
5/10/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998835	ETH.MESH.05998836
5/13/2012	de Leval J email chain re Alerte TVT Abbrevio	ETH.MESH.07318311	ETH.MESH.07318313
5/14/2012	Vellucci email re 522 Guidance Document Gynecare Prosima	ETH.MESH.05600730	ETH.MESH.05600731
5/15/2012	Master Consulting Agreement between Melvyn A. Anhalt and Ethicon	ETH.MESH.08065931	ETH.MESH.08065943
5/29/2012	Background Information Gynecare Pelvic Floor Repair Products and Gynecare TVT Scrue	ETH.MESH.05600916	ETH.MESH.05600923
6/4/2012	PFT / TVT Secur Discontinuation: Current State - Presentation	ETH.MESH.19223769	ETH.MESH.19223773
6/14/2012	TVT-172-12-6/14 Patient Brochure - Stop Coping. START LIVING. WHAT YOU SHOULD KNOW ABOUT STRESS URINARY INCONTINENCE	ETH.MESH.05815791	ETH.MESH.05815802
6/16/2012	ARTISYN Advisory Board notes	ETH.MESH.09158424	ETH.MESH.09158430
7/26/2012	Email Piet Hinoul to Axel Arnaud re article "The perils of commercially driven surgical innovation"	ETH.MESH.05125293	ETH.MESH.05125297
8/6/2012	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh	ETH.MESH.13376756	ETH.MESH.13376758
8/6/2012	Primary Blister Defect Definitions and Classifications Release Level: 4. Production	ETH.MESH.13376759	ETH.MESH.13376768
8/7/2012	Chen M email chain re New Complaint Form 23125	ETH.MESH.09478633	ETH.MESH.09478636
8/7/2012	Doyle email chain re Surgeon request for follow up 10100175641	ETH.MESH.11529265	ETH.MESH.11529266
8/20/2012	Chen M email chain re Urgent - MDR serious injuries Gynecare France	ETH.MESH.09478684	ETH.MESH.09478688
9/25/2012	Gynecare PROLIFT +M Pelvic Floor Repair System	ETH.MESH.8315779	ETH.MESH.8315810

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9/28/2012	Letter Benjamin R. Fisher PhD (Department of Health & Human Services) to Susan Lin re Gynecare TVT Abbrevio Continence System K100936 re marketing device	ETH.MESH.10039685	ETH.MESH.10040061
10/1/2012	Gynecare TVT Abbrevio Salees Aid TVTA 325-12	ETH.MESH.13681528	ETH.MESH.13681528
10/15/2012	TVT 20121015 Stop Coping Start Living . . .	ETH.MESH.9744848	ETH.MESH.9744855
12/10/2012	TVT 20121210 Stop Coping Start Living . . .	ETH.MESH.9744858	ETH.MESH.9744863
1/6/2013	Amin D Gynecare Protfolio Presentation	ETH.MESH.03685918	ETH.MESH.03685925
1/11/2013	Chung email chain re Gynecare RFP	ETH.MESH.13374555	ETH.MESH.13374558
1/21/2013	Tait email chain re Non conform lids	ETH.MESH.14348386	ETH.MESH.14348388
1/30/2013	CAPA-002157	ETH.MESH.15137959	ETH.MESH.15137967
2/14/2013	TVT 20130214 Stop Coping Start Living . . .	ETH.MESH.9744840	ETH.MESH.9744845
2/15/2013	Connaughton email chain re New litigation Prolift & TVT	ETH.MESH.13274846	ETH.MESH.13274847
2/15/2013	Connaughton email chain re new litigation Prolift & TVT	ETH.MESH.13274855	ETH.MESH.13274856
2/18/2013	Journot memo re CAPA130022 - Defective percentage justification	ETH.MESH.15137979	ETH.MESH.15137979
2/23/2013	Roseleip email chain re TVT Heads up	ETH.MESH.08422124	ETH.MESH.08422125
3/8/2013	CAPA#130022 - Repetition of NCR for particles - Team Meeting Minutes	ETH.MESH.15137986	ETH.MESH.15137987
3/20/2013	Revision History of MS-0000108	ETH.MESH.10633520	
3/20/2013	Connaughton email chain re New litigation TVT	ETH.MESH.13208194	ETH.MESH.13208196
3/26/2013	Rahman communication - AUGS Issues Statement Opposing the Restriction of Surgical Options for Pelvic Floor Disorders	ETH.MESH.08073801	ETH.MESH.08073803
4/23/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02341954	ETH.MESH.02341954
4/25/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02342194	ETH.MESH.02342194
4/26/2013	Clinical Expertise - The Evolution of Sub-urethral Slings for the Surgical Corrector of Female Stress Urinary Incontinence (SUI) Obturator	ETH.MESH.13739540	ETH.MESH.13739540
5/3/2013	TVT 20130503	ETH.MESH.09744870	ETH.MESH.09744871
5/3/2013	Hinoul Clinical Evaluation Report	ETH.MESH.10287104	ETH.MESH.10287439
5/3/2013	TVT 20130503 Gynecare TVT Obturator - Mesh Placement for Patient Consult	ETH.MESH.9744870	ETH.MESH.9744871
5/7/2013	TVT 20130507 Gynecare TVT Abbrevio - Mesh Placement for Patient Consult	ETH.MESH.9744866	ETH.MESH.9744867
5/8/2013	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family	ETH.MESH.09909830	ETH.MESH.09909882
5/22/2013	GGM Blue Database Export TVT Obturator Brochure	ETH.MESH.13700031	ETH.MESH.13700032

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5/23/2013	Connaughton email chain re New litigation	ETH.MESH.13259844	ETH.MESH.13259845
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14852591	ETH.MESH.14852592
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14901756	ETH.MESH.14901757
6/13/2013	Journot email chain re Design Impact assessment ADAPTIV - Creation of change project	ETH.MESH.13457716	ETH.MESH.13457718
6/19/2013	Issue Reports Open Date BEtween 01-Jan-2005 and 02-Jun-2013	ETH.MESH.09732998	ETH.MESH.09733718
6/19/2013	GGM Blue Database Export Project ID: 417127 TVTO-426-13	ETH.MESH.13704931	ETH.MESH.13704932
6/21/2013	Weisberg email chain re TVT mesh elongation FW: Dr. Kenny Maslow	ETH.MESH.12910023	ETH.MESH.12910026
6/21/2013	Weisbert email chain re TVT mesn elongation FW: Dr. Kenny Maslow	ETH.MESH.12910030	ETH.MESH.12910032
6/25/2013	Weisberg email chain re TVT mesh enlongation - Redacted	ETH.MESH.12910111	ETH.MESH.12910113
6/27/2013	Ex T-722 Mltchell - Clinical Expert Report Gynecare Prolift +M	ETH.MESH.08315779	ETH.MESH.08315810
7/2/2013	Connaughton email chain re new litigation TVT-O	ETH.MESH.14908784	ETH.MESH.14908785
7/15/2013	Connaughton email chain re New litigation TVT-O	ETH.MESH.14967284	ETH.MESH.14967285
7/19/2013	Clinical Evaluation Report Gynecare TVT Family of Products	ETH.MESH.10150515	ETH.MESH.10150849
8/5/2013	Amin email chain re HPG Pelvic Floor RFP	ETH.MESH.12877116	ETH.MESH.12877117
8/19/2013	Finch email chain re New litigation TVT-S	ETH.MESH.13292806	ETH.MESH.13292807
8/28/2013	Hinoult email re MIR TVT - ilioninguinal pain w/attachment	ETH.MESH.12913351	ETH.MESH.12913356
9/17/2013	Librojo email chain re Copy Review Exception	ETH.MESH.12906504	ETH.MESH.12906506
9/21/2013	Gallo email chain re new litigation TVT	ETH.MESH.13296239	ETH.MESH.13296240
9/26/2013	CAPA File - Protocol to migrate CAPAs from PLM to ETQ Application	ETH.MESH.15137968	ETH.MESH.15137968
9/30/2013	Angelini Browse JJEDS Object Detail form	ETH.MESH.10591939	ETH.MESH.10591949
11/7/2013	Jacobs email chain re defect to harms map	ETH.MESH.12907174	ETH.MESH.12907174
11/7/2013	McNelis email new litigation TVT	ETH.MESH.15034561	ETH.MESH.15034562
11/9/2013	Finch email re new litigation TVT	ETH.MESH.14896228	ETH.MESH.14896229
12/8/2013	Finch email chain re Addtl Info New Litigation Prosima & TVT-O	ETH.MESH.14913573	ETH.MESH.14913575
12/8/2013	Finch email chain re Addtl Info new litigation Prosima & TVT-O	ETH.MESH.14994654	ETH.MESH.14994656
1/6/2014	Killins email chain re Addtl info - new litigation TVT & Prosima	ETH.MESH.14852593	ETH.MESH.14852595
1/6/2014	Killins email chain re Addtl info new litigation TVT & Prosima	ETH.MESH.14901758	ETH.MESH.14901760
1/8/2014	TVTO_366_13_TVT Obturator Brochure	ETH.MESH.13700033	ETH.MESH.13700037
1/9/2014	Corrado email re QRB presentation	ETH.MESH.17640736	ETH.MESH.17640767
1/10/2014	Hinoult P email re Abbrevio MIR	ETH.MESH.16359412	ETH.MESH.16359412
1/30/2014	Tran email chain re addtl info - Prosima & TVT-O	ETH.MESH.14913576	ETH.MESH.14913578

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1/30/2014	Tran email chain re Addtl Info -	ETH.MESH.14994657	ETH.MESH.14994659
1/31/2014	Jackson email chain Addtl Info -	ETH.MESH.14967286	ETH.MESH.14967287
2/3/2014	Mesh Slide T-3581	ETH.MESH.00584179	ETH.MESH.00584179
2/4/2014	Piper email chain re Addtl info	ETH.MESH.14896230	ETH.MESH.14896232
2/6/2014	Sedlatschek email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.16357097	ETH.MESH.16357097
2/7/2014	Tran email chain re addtl info 1/30/14	ETH.MESH.14896233	ETH.MESH.14896235
2/7/2014	Sedlatschek email re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17777763	ETH.MESH.17777768
2/27/2014	Revision Hx 100193881	ETH.MESH.22852060	ETH.MESH.22852063
3/26/2014	Rodriguez email chain re Nilsson 2013	HMESH_ETH_06033196	HMESH_ETH_06033202
3/27/2014	Rodriguez email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17619399	ETH.MESH.17619405
4/7/2014	Dear Dr. Itr re unsolicited request for medical/scientific information - Gynecare TVT Abbrevio	ETH.MESH.16354541	ETH.MESH.16354545
4/11/2014	Hinour P email chain re TVT Abbrevio medical information request	ETH.MESH.16359598	ETH.MESH.16359598
4/14/2014	PQI Revision 10	ETH.MESH.17642669	ETH.MESH.17642686
4/14/2014	Elbert email chain re Candad - TVT RFQ	ETH.MESH.19125383	ETH.MESH.19125385
5/19/2014	Rodriguez email chain re UPDATE to Escalation Notice - Section 39 Request - TVT, Gynemesh PS & Artisyn Y-Shared Mesh	ETH.MESH.17777759	ETH.MESH.17777762
10/2/2014	Smith email re TVT Products	ETH.MESH.19125531	ETH.MESH.19125531
2/17/2015	List of Preceptor Names and Events Attended	ETH.MESH.03625982	ETH.MESH.03625982
6/1/2015	Ethicon UK Gynaecology Complaints email re Customer Ref 2015/005/020/104/005 Request for Information	ETH.MESH.22646295	ETH.MESH.22646296
??/??/02	CER Update for TVT	ETH.MESH.00340836	ETH.MESH.00340838
??/??/02	Hellhammer et al. Scientific Statement - Shrinking Meshes?	ETH.MESH.05446129	ETH.MESH.05446132
??/??/03	Contact Points - Nummular allergic contact dermatitis after scabies treatment, R. Kaminska, et al	HMESH_ETH.07269753	HMESH_ETH.07269765
??/??/07	Brochure "Find out how to stop urine leakage like Bonnie did"	ETH.MESH.00163582	ETH.MESH.00163597
??/??/07	Gynecare TVT Secur Competitive Product Update	ETH.MESH.01805958	ETH.MESH.01805958
??/??/07	Basell Purell MSDS	ETH.MESH.06861946	ETH.MESH.06861946
??/??/07	TVT 20070531 Patient Brochure - The Choice to End Stress Urinary Incontinence Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003247	ETH.MESH.08003262
??/??/08	Brochure The Gynecare TVT Family of Products 3 SUI Solutions. Delivering Data, Safety & Choice.	ETH.MESH.00658453	ETH.MESH.00658458
??/??/08	ANSI/AAMI/ISO 10993-7:2008	ETH.MESH.07474296	ETH.MESH.07474407
??/??/09	Stop coping. Start living	ETH.MESH.00002162	ETH.MESH.00002177
??/??/09	P15506 Gynecare TVT IFU	ETH.MESH.02340402	ETH.MESH.02340470

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??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.00270802	ETH.MESH.00270821
??/??/10	2010 preceptor payments spreadsheet	ETH.MESH.00499024	ETH.MESH.00499024
??/??/10	Physician patient follow-up form letter	ETH.MESH.02236784	ETH.MESH.02236785
??/??/10	R&D CO-OP Welcome Guide Spring 2010	ETH.MESH.06260647	ETH.MESH.06260671
??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.08614017	ETH.MESH.08614021
??/??/11	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair	ETH.MESH.04005863	ETH.MESH.04006038
??/??/11	2011 Price List	ETH.MESH.17556578	ETH.MESH.17556579
??/??/12	Sales spreadsheet	ETH.MESH.08078799	ETH.MESH.08078799
??/??/12	TVT-312-12 Patient Brochure - stop coping. start living. GYNECARE TVT Family of Products	ETH.MESH.09744848	ETH.MESH.09744855
??/??/13	TVT-131-13 Patient Brochure - stop coping start living. What You Should Not About Stress Urinary Incontinence	ETH.MESH.09744840	ETH.MESH.09744845
??/??/13	TVT Abbrevio information pamphlet	ETH.MESH.09744866	ETH.MESH.09744867
??/??/14	Product cost analysis	ETH.MESH.06767981	ETH.MESH.06767983
??/??/14	Total Units Sold Chart	T-1499	T-1499
??/??/2006	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
??/??/2009	Mini TVT-O Claim Development	ETH.MESH.00345842	ETH.MESH.00345842
??/??/2010	Draft 510(k) premarket Abbrevio	ETH.MESH.00343379	ETH.MESH.00343442
??/??/2010	The efficacy she needs with less mesh - annotated - round 3	ETH.MESH.00346194	ETH.MESH.00346201
??/??/2010	The efficacy she needs with less mesh	ETH.MESH.11434264	ETH.MESH.11434272
??/??/2011	Competitive Dissection Flashcard	ETH.MESH.00790545	ETH.MESH.00790546
??/??/2011	Ethicon Neuchâtel A changing Product Protfolio	ETH.MESH.14273633	ETH.MESH.14273668
??/??/2012	Frequently Asked Questions Clinical Data Review 3-Year Data Flashcard	ETH.MESH.07808484	ETH.MESH.07808486
??/??/2012	DSL Clinical Article Waltregny - New Surgical Technique for Tx of SUI TVT-Abbrevio . . .	ETH.MESH.16289560	ETH.MESH.16289569
??/??/2012	Evaluation of the Fixation of Gynecare TVT Abbrevio Continence System as Compared to Gynecare TVT Obturatory System Tension-Free Support for Incontinence in Human Cadaveric Model - Presentaiton	ETH.MESH.16426660	ETH.MESH.16426660
??/??/2013	Patient Brochure	ETH.MESH.16308087	ETH.MESH.16308090
00/0/0000	Consultancy Agreement	ETH.MESH.9748842	ETH.MESH.9748846
00/00/0000	Gynecare TVT Patient Brochure stop coping. start living	ETH.MESH.2236580	ETH.MESH.2236595
00/00/0000	Spanish Gynecare TVT Patient Brochure, translated from Gynecare TVT English Patient Brochure	ETH.MESH.2237665	ETH.MESH.2237696
00/00/0000	Definition for Major Invasive Surgeries	ETH.MESH.321804	ETH.MESH.321805
00/00/0000	Gynecare Pro-lift Ad.	ETH.MESH.3905968	
00/00/0000	Medscand Agreement Files	ETH.MESH.8696085	ETH.MESH.8696134
00/00/0000	Consultancy Agreement	ETH.MESH.9748848	ETH.MESH.9748853

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00/00/2002	CER Update for TVT 06/15/2000	ETH.MESH.340836	ETH.MESH.343838
00/00/2004	Memo from London Brown to D. Smith re Mechanical Cut vs. Laser Cut Mesh Rationale	ETH.MESH.858252	ETH.MESH.858253
00/00/2007	Gynecare TVT Secure Competitive Produce Update 2007 Power Point Presentation	ETH.MESH.1805958	
00/00/2007	PE GF 4750 Purell PP technical data info	ETH.MESH.6861946	
00/00/2008	ANSI/AAMI/ISO 10993-7:2008 EO residual ISO testing American National Standard Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals	ETH.MESH.7474296	ETH.MESH.7474407
00/00/2010	Physician patient follow-up form letter	ETH.MESH.2236784	ETH.MESH.2236785
00/00/2011	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair	ETH.MESH.4005863	
00/00/2012	TVT 2012 Stop Coping Start Living . . . TVT-172-12-6/14	ETH.MESH.5815791	ETH.MESH.5815802
01/??/02	DTC Advertising Patient Potential January 2002 Presentation	ETH.MESH.08793554	ETH.MESH.08793554
01/??/08	Working copy - Communications to Surgeons re TVT SECUR	ETH.MESH.00318311	ETH.MESH.00318312
02/??/02	5 Years of Proven Performance TVT Sales Aid (TVT041)	ETH.MESH.00339437	ETH.MESH.00339442
03/??/02	Worldwide Clinical Trials, Medical Affairs Gynecare - Monthly Report	ETH.MESH.07387082	ETH.MESH.07387103
03/??/07	CAPA 070015 Trending and tracking system - presentation	ETH.MESH.14708986	ETH.MESH.14709011
03/??/11	ETHICON Polypropylene Mesh Technology- Batke presentation	ETH.MESH.05479717	ETH.MESH.05479717
04/??/00	European Clinical R&D Monthly Report	ETH.MESH.05493782	ETH.MESH.05493810
04/??/08	Klosterhalfen Interim report mesh explants pelvic floor repair	ETH.MESH.00006636	ETH.MESH.00006636
04/??/1989	Ethicon, Inc. Book No. 3077	ETH.MESH.15143734	ETH.MESH.15143821
05/??/12	Quality Operation Review Trend Analysis Metrics - presentation	ETH.MESH.22754103	ETH.MESH.22754142
06/??/00	TVT Surgeons Resource Monograph	ETH.MESH.00400957	ETH.MESH.00400978
06/??/02	Monthly Report WW Clinical Research Activities Gynecare	ETH.MESH.05490280	ETH.MESH.05490311
06/00/2000	TVT Surgeons Resource Monograph	ETH.MESH.400957	ETH.MESH.400978
07/??/09	BUC July 2009 I&pf platforms	ETH.MESH.05764101	ETH.MESH.05764101
07/??/12	FDA Communication re PS120095 GYNECARE TVT Secur System - Amended: 05032012	ETH.MESH.11333804	ETH.MESH.11333805
07/??/2012	Claims for Gynecare TVT Abbrevo spreadsheet	ETH.MESH.00346665	ETH.MESH.00346667
08/??/09	HS Study Monthly Update	ETH.MESH.00533025	ETH.MESH.00533026

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08/??/2010	Clinical Data Review Presented at ICS/IUGA Aug 2010	ETH.MESH.03422160	ETH.MESH.03422162
09/??/04	Physician Segmentation Study for Gynecare TVT Final Presentation - Copernicus	ETH.MESH.03571983	ETH.MESH.03572098
09/??/07	Pleiger - Polyamid.nylon MSDS	H.MESH.ETH.0066036	H.MESH.ETH.0066078
09/??/10	Neuchatel - September 2010 Roles and Responsibilities	ETH.MESH.09932902	ETH.MESH.09932912
09/??/10	Neuchatel - September 2010 Roles and Responsibilities	ETH.MESH.09932908	ETH.MESH.09932918
10/??/00	TVT Update Success & Complications - Bernard Jacquetin	ETH.MESH.04044797	ETH.MESH.04044800
10/??/03	Gynecare 7 Year Data Indicates Strong Continued Safety and Effectiveness for GYNECARE TVT Tension-free Support for Incontinence	ETH.MESH.05794787	ETH.MESH.05794788
10/??/08	IFPM position on FDA notification	ETH.MESH.17556582	ETH.MESH.17556582
10/??/2012	Clinical Data Review - 3 year data	ETH.MESH.07808480	ETH.MESH.07808481
2/28/060	Email from David Robinson re tvt o training	ETH.MESH.846523	
N/A	Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621559 at 02622276	
	Summary of 63 TVT-O RCTs - Batiste Defense Trial Exhibit	D23501.1	
	Mesh Weight Chart	Deposition Exhibit	
	Toglia presentation, The Mesh Story	ETH.MESH..16432550	ETH.MESH..16432550
	Annotated Prolift +M List of potential claims	ETH.MESH.00008631	ETH.MESH.00008631
	Letter of Proffer: Madigan Army Medical Center	ETH.MESH.00010743	ETH.MESH.00010743
	Prolift - Level One Mesh Course	ETH.MESH.00057142	ETH.MESH.00057146
	Franco Naples, FL Presentation - The Science of "What's Left Behind" . . .	ETH.MESH.00057515	ETH.MESH.00057531
	Voicemail from Kevin Mahar to EWH&U Sales & Marketing Organization re FDA PHN Product defect	ETH.MESH.00066960	ETH.MESH.00066960
	Presentation: Gynecare Prolift+M Pelvic Floor Repair System Training	ETH.MESH.00074499	ETH.MESH.00074499
	Feeney letter re Secondary Sales School #7	ETH.MESH.00140431	ETH.MESH.00140452
	Presentation draft - Tension-Free Support for Female SUI (258 Patients) - Modarelli, et al	ETH.MESH.00143842	ETH.MESH.00143842
	7 year Data Press Release - New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates	ETH.MESH.00155598	ETH.MESH.00155600
	Toth Memo w/ Gynecare TVT Professional Education Slides	ETH.MESH.00159634	ETH.MESH.00159719
	TVT Detail Sheet (TVTOO1R	ETH.MESH.00161444	ETH.MESH.00161445
	Final FDA Notification about Use of Surgical Mesh to Treat Pelvic Organ Prolapse and Stress Urinary Incontinence Standby for Media/Analyst inquiries	ETH.MESH.00164023	ETH.MESH.00164025

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	Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
	Email Sandy Savidge to Donna Taggart re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211259	ETH.MESH.00211260
	Email Susan Lin re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211263	ETH.MESH.00211265
	DHF0000747 TVT Retropublic Refresh	ETH.MESH.00223634	ETH.MESH.00223655
	Spreadsheet TVT Retropublic Refresh	ETH.MESH.00223640	ETH.MESH.00223640
	Powerpoint TVT Retropublic Refresh	ETH.MESH.00223800	ETH.MESH.00223800
	Design Input Strategy Project Mulberry by Dan Smith	ETH.MESH.00259269	ETH.MESH.00259274
	Clinical Expert Report - Weisberg Assessment of the "inside-Out" Transobturator Approach to Implant . . .	ETH.MESH.00259634	ETH.MESH.00259644
	Franco presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.00271641	ETH.MESH.00271641
	Lamont email chain re !!!!Great News for TVT Laser Cut Mesh!!!!	ETH.MESH.00301741	ETH.MESH.00301742
	TVT Laser Cut Mesh Project Revision History for DFMEA0000242	ETH.MESH.00301977	ETH.MESH.00301977
	Maree, A email chain re AUSA update and telephone call with Prof Frazer	ETH.MESH.00311792	ETH.MESH.00311794
	Presentation: Investigator Initiated Study Process by Kimberly Hunsicker, MSN, CRNP Regional Manager, Clinical Operations	ETH.MESH.00311832	ETH.MESH.00311848
	Manley email chain re Project priorities for WH&U #1 TVT-Secur, #2 Laser cut TVT #3 Mint, #4 PROFIX	ETH.MESH.00321229	ETH.MESH.00321230
	Definition for Major Invasive Surgeries and The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation	ETH.MESH.00321804	ETH.MESH.00321805
	Yale email chain re TVT-S Update	ETH.MESH.00326882	ETH.MESH.00326884
	Email Jennifer Paine to Catherine Beath, et al. re FDA Public Health Notice on Surgical Mesh for POP and SUI - URGENT	ETH.MESH.00329112	ETH.MESH.00329113
	Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00340835	ETH.MESH.00340835
	Hinoul P, Synopsis of preclinical data in support of TVT Abbrevo's equivalence to TVT-O	ETH.MESH.00346427	ETH.MESH.00346439
	Spreadsheet TVT Secur dFMEA Rev #1	ETH.MESH.00349122	ETH.MESH.00349122
	Abbrevo FAQs -	ETH.MESH.00350696	ETH.MESH.00350696
	Annotated Slide	ETH.MESH.00353476	ETH.MESH.00353476
	Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354724	ETH.MESH.00354724
	Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725
	Differentiation Statement	ETH.MESH.00355435	ETH.MESH.00355435
	Review of Surgical Techniques Using Mesh, Robinson presentation	ETH.MESH.00396836	ETH.MESH.00396868
	Ulmsten letter to Rick	ETH.MESH.00400954	ETH.MESH.00400956

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	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00401213	ETH.MESH.00401217
	Customer Initiated Research Grant Request (Wang)	ETH.MESH.00409659	ETH.MESH.00409663
	Letter from Martin Weisberg re 7 Year Data Indicates Strong Continued Safety and Effectiveness for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00524444	ETH.MESH.00524445
	Product Quality Plan for Gynecare Gynemesh XL	ETH.MESH.00528636	ETH.MESH.00528641
	Annotated - Evaluation of the Fixation of TVT Abbrevo as compared to TVT-O in a Human Cadaveric Model	ETH.MESH.00576887	ETH.MESH.00576888
	Gynecare International Convention Recommendations	ETH.MESH.00581483	ETH.MESH.00581486
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00589494	ETH.MESH.00589494
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
	Gynecare TVT Sales Representative quick reference sheet	ETH.MESH.00640394	ETH.MESH.00640395
	Robinson email chain re TVT) versus TVT Secur efficacy and safety rates	ETH.MESH.00647404	ETH.MESH.00647409
	Mahar email chain re Continued Positive Feedback on LCM from EMEA - Rep Survey & Customer Guarantee attached	ETH.MESH.00708653	ETH.MESH.00708655
	Product Pointer	ETH.MESH.00746209E TH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00748275	ETH.MESH.00748275
	K012628 TVT Blue System and Accessory TVT-AA	ETH.MESH.00748310	ETH.MESH.00748450
	abbrevo afmea rev a	ETH.MESH.00754439	ETH.MESH.00754446
	Email David Robinson to Giselle Bonet re forgot	ETH.MESH.00756984	ETH.MESH.00756984
	Memo to Jacqueline Russo from Ogilvy Public Relations	ETH.MESH.00766347	ETH.MESH.00766349
	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
	Email from David Robinson (Medical Director) re Risk/Benefit Analysis for TVT SECUR Clinical Expert Report	ETH.MESH.00823660	ETH.MESH.00823660
	Product Complaints Graph	ETH.MESH.00826046	ETH.MESH.00826047
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	Product Flowchart	ETH.MESH.00858891	ETH.MESH.00858891
	PT0-0746; Version 1 Validation Protocol for Knitting, Scouring and Heat-Setting 6-mil Old Construction Blue PROLENE Mesh at Secant Medical	ETH.MESH.00862227	ETH.MESH.00862235
	MS729-XXX; Appendix 1	ETH.MESH.00862284	ETH.MESH.00862289

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Presentation: SUI, A Primary Care Perspective	ETH.MESH.00995657	ETH.MESH.00995657
Complaint Reporting Statement	ETH.MESH.00995835	ETH.MESH.00995836
Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
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Spreadsheet DFMEA's TVT Classic	ETH.MESH.01068862	ETH.MESH.01068862
Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
Hinoul - IUGA From presentation to publication: ensuring quality in the reporting of urogynaecology research	ETH.MESH.01186613	ETH.MESH.01186613
New Structures to create for GYNECARE TVT ABBREVO™ Anatomy Modules	ETH.MESH.01188589	ETH.MESH.01188613
Abbrevio Professional Education Presentation	ETH.MESH.01201957	ETH.MESH.01201957
Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
TVT-Abbrevio RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099
Memo by Lynn Hall re Summary of Findings and Next Steps from 10.12.01 TVT DTC Focus Groups	ETH.MESH.01217285	ETH.MESH.01217288
Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
TVT Laser Cut Mesh Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
An independent biomechanical evaluation of commercially available suburethral slings Article	ETH.MESH.01221055	ETH.MESH.01221058
Dr. Letter	ETH.MESH.01226446	ETH.MESH.01226449
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01247379	ETH.MESH.01247379
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01250926	ETH.MESH.01250926
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Spreadsheet re Faculty, Preceptors, Speaking Training, etc.	ETH.MESH.01674264	ETH.MESH.01674264
Trzewik - Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
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VOC Summary Mini Me - Presentation	ETH.MESH.01816436	ETH.MESH.01816436
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Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
Division Meeting Notes: Continence Health	ETH.MESH.02108293	ETH.MESH.02108295
Memo to Rippy re Mechanisms of Cytotoxicity for TVT Polypropylene Mesh	ETH.MESH.02134271	ETH.MESH.02134273
Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
Completion Report, Design Verificaiton for Soft PROLENE Mesh/Mesh Curling	ETH.MESH.02182839	ETH.MESH.02182844
Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
Design Verification Protocol for TVT-O PAC [TOPA Clinical] Project 14495, Version 1 Study Number AST-2010-0536	ETH.MESH.02221369	ETH.MESH.02221378
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Patient Brochure - Stop coping. Start Living. Gynecare TVT Family of Products	ETH.MESH.02236580	ETH.MESH.02236595
Spanish Gynecare TVT patient brochure	ETH.MESH.02237665	ETH.MESH.02237696
New Product Introduction Presentation	ETH.MESH.02249435	ETH.MESH.02249435
Vellucci, L emal chain re Ethicon sponsored study	ETH.MESH.02252005	ETH.MESH.02252007
Spreadsheet DFMEA's TVT Classic	ETH.MESH.02265802	ETH.MESH.02265802
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Pompilio S email re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.02310653	ETH.MESH.02310657
TVT IFU through	ETH.MESH.02340306	ETH.MESH.02340369
TVT IFU through	ETH.MESH.02340504	ETH.MESH.02340567
Prolene	ETH.MESH.02342102	ETH.MESH.02342102
TVT - Freedom From Stress Urinary Incontinence	ETH.MESH.02619504	ETH.MESH.02619511
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TVT Classic 2002	ETH.MESH.02623743	
TVT Classic 2003 Issue Report	ETH.MESH.02625055	ETH.MESH.02626377
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Issue Report TVT-O 2010 Open Date Between 01-Jan-2006 and 31-Dec-2006	ETH.MESH.02654027	ETH.MESH.02654034
Issue Report TVT-O 2010 Open Date Between 01-Jan-2010 and 31-Dec-2010	ETH.MESH.02656825	ETH.MESH.02656834
Robinson email chain re Pelvic Floor/Mesh Strategy	ETH.MESH.03160750	ETH.MESH.03160752
Run on eg log.txt	ETH.MESH.03334244	ETH.MESH.03334244
TVT IFU to present	ETH.MESH.03427878	ETH.MESH.03427946
Patient advertisement for TVT "One day you have urine leakage. The next day you don't. End of story."	ETH.MESH.03460640	ETH.MESH.03460640
Physician form letter re RVR51 - Gynecare TVT Secur System	ETH.MESH.03509755	ETH.MESH.03509755
Holloway ltt Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
Consulting Agreement between Dr. Brian Flynn and Ethicon	ETH.MESH.03605457	ETH.MESH.03605463
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510(k) Premarket Notification GYNECARE TVTO-PA Continence System	ETH.MESH.03654649	ETH.MESH.03654701
MS455-012; Revision 18 Material Specification for Pelletized Unpigmented	ETH.MESH.03671138	ETH.MESH.03671147
Email Martin Weisberg to Barbara McCabe re leVal	ETH.MESH.03715571	ETH.MESH.03715574
Check Liste D'Inspection Qualite - Final TVT-TVT-AA	ETH.MESH.03730703	ETH.MESH.03730722
Emails Martin Weisberg and Dr Peggy Norton re TVT	ETH.MESH.03738466	ETH.MESH.03738467
Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168
Gynecare Pro-lift Ad "Get the Facts, Be Informed, Make YOUR Best Decision"	ETH.MESH.03905968	ETH.MESH.03905975
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2.0 Products in Development	ETH.MESH.03924530	ETH.MESH.03924539
History of TVT-O	ETH.MESH.03932909	ETH.MESH.03932911
The history of TVT	ETH.MESH.03932912	ETH.MESH.03932914
Presentation: "The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Use for SUI by Doug H. Grier, MD"	ETH.MESH.03965159	ETH.MESH.03965195
Presentation: TVTO Data 2006 & 2007 Ethicon Women's Health & Urology, The Netherlands	ETH.MESH.04049320	ETH.MESH.04049320
Marketing & Launch Plan	ETH.MESH.04061003	ETH.MESH.04061048
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Chen, Medical Assessment - . . . 68 issues from Germany	ETH.MESH.04081871	ETH.MESH.04081872
Study Notes, Meng Chen, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse	ETH.MESH.04082973	ETH.MESH.04082974
Email Meng Chen to Carolyn Brennan re TVTs and bladder perforation	ETH.MESH.04090122	ETH.MESH.04090122
Email Meng Chen to Sergio Gadaleta, et al. re #10100080654 and TVT IFUs	ETH.MESH.04092868	ETH.MESH.04092869
Particles in TVTO Blisters presentation	ETH.MESH.04101824	ETH.MESH.04101824
Check Liste D'Inspection Qualite	ETH.MESH.04321393	ETH.MESH.04321396
Check Liste D'Inspection Qualite	ETH.MESH.04321397	ETH.MESH.04321400
Check Liste D'Inspection Qualite	ETH.MESH.04321401	ETH.MESH.04321404
Check Liste D'Inspection Qualite	ETH.MESH.04321405	ETH.MESH.04321408
Check Liste D-Inspection Qualite	ETH.MESH.04321409	ETH.MESH.04321412
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LIGHTning Project Charter - Meier et al presentation	ETH.MESH.05237336	ETH.MESH.05237382
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Materials - defect spreadsheet	ETH.MESH.05514963	ETH.MESH.05514963
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Presentation: Solving the Device Design Puzzle	ETH.MESH.05918082	ETH.MESH.05918116
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	Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05973195	ETH.MESH.05973200
	Savidge email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	ETH.MESH.06015836	ETH.MESH.06015839
	TVT-444-10-11/12 Patient brochure - stop coping. start living. As yourself . . . Are you suffering from any of these syptoms?	ETH.MESH.06087471	ETH.MESH.06087472
	Spreadsheet	ETH.MESH.06171801	ETH.MESH.06171801
	Divilio memo	ETH.MESH.06195201	ETH.MESH.06195205
	Dodd presentation: TVT: Insights into the Making of a Revolution	ETH.MESH.06859904	ETH.MESH.06859931
	Gynecare TVT-S Competitive Product Update	ETH.MESH.06861473	ETH.MESH.06861473
	Kammerer email re Ultra sonic slit TVT	ETH.MESH.06866919	ETH.MESH.06866919
	ETH.MESH.06866921 attachment	ETH.MESH.06866921	ETH.MESH.06866921
	Presentation - Scion PP	ETH.MESH.06921531	ETH.MESH.06921531
	Memo Evaluation of the Mesh Elongation, Function of Number of Wales	ETH.MESH.06926711	ETH.MESH.06926714
	FDA Communication re PS120095 GYNECARE TVT Secur System	ETH.MESH.07218087	ETH.MESH.07218088
	Biocompatibility Risk Assessment: PROSIMA Pelvic Floor Repair System (Mint)	ETH.MESH.07506983	ETH.MESH.07506985
	Presentation: Sicon PA Commercial Strategy	ETH.MESH.07903520	ETH.MESH.07903520
	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	ETH.MESH.07937826	ETH.MESH.07937828
	TVVT016R9 Patient brochure - stop coping. start living	ETH.MESH.08003279	ETH.MESH.08003294
	Presentation TVT Abbrevio Incontinence System Professional Education by Dr. Grier	ETH.MESH.08004035	ETH.MESH.08004035
	Grier Consulting Agreement Requisition Form	ETH.MESH.08007502	ETH.MESH.08007512
	Hurricane and The Stars Divisional Meeting Orlando Marriott World Center Agenda	ETH.MESH.08050183	ETH.MESH.08050183
	Emails Dr. Brigitte Hellhammer to Dr. Hans-Jochen Hoepffner, et al. re Cardozo Trial	ETH.MESH.08167644	ETH.MESH.08167645
	LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh	ETH.MESH.08334245	ETH.MESH.08334245
	Mahar email chain re Contact at Lifescan who ran the BB King campaign	ETH.MESH.08345895	ETH.MESH.08345895
	TVT Obturator System Product Description	ETH.MESH.08376560	ETH.MESH.08376564
	Toglia Presentation - The Mesh Story working copy	ETH.MESH.08426862	ETH.MESH.08426867
	Cecchini TVT package insert comments	ETH.MESH.08505071	ETH.MESH.08505071
	Medhekar email chain re Ethicon Mesh DVD - FDA Request Follow-Up	ETH.MESH.08516130	ETH.MESH.08516132
	Zaddem email re cannulae metal particles	ETH.MESH.08561511	ETH.MESH.08561511
	Kirkemo ltr to Dr. Kondrup re request for information	ETH.MESH.08570968	ETH.MESH.08570970

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	Equivalence Supported by Pre-clinical Performance Studies	ETH.MESH.08581280	ETH.MESH.08581282
	Literature on TVT-O sling and pain management	ETH.MESH.08584142	ETH.MESH.08584143
	Franchise Procedure for Controlling Substances of Concern Revision History PR-0000558	ETH.MESH.08664680	ETH.MESH.08664686
	Cancellation Agreement between Ethicon, Inc., Contape S.A., and the estate of Professor Ulf Ivar Ulmsten	ETH.MESH.08692670	ETH.MESH.08692672
	Consulting Agreement between Ethicon, Inc. and Contape S.A. and Professor Ulf Ivar Ulmsten	ETH.MESH.08692673	ETH.MESH.08692696
	Medscand Agreement Files	ETH.MESH.08696085	ETH.MESH.08696134
	Instruction Standard TVT EXACT product Plan and Rationald Appendix I, Revision A	ETH.MESH.08776231	ETH.MESH.08776238
	Nonnenmann Performance Evaluation - Memo re TVT+M Mesh Tensile Strength	ETH.MESH.08776793	ETH.MESH.08776794
	RMR - LCM Revision 2	ETH.MESH.08792102	ETH.MESH.08792106
	Cario email chain re Dr. Wang's proposal	ETH.MESH.08793207	ETH.MESH.08793210
	Ailawadi - Does Material Matter - final	ETH.MESH.08968369	ETH.MESH.08968378
	Elongation test data	ETH.MESH.09004554	ETH.MESH.09004554
	Elongation test data - delayed launch	ETH.MESH.09004555	ETH.MESH.09004555
	Savidge S email chain re 510k Mint tests pending	ETH.MESH.09052531	ETH.MESH.09052534
	Operation Abbrevo Combat Training Splash Storyboard	ETH.MESH.09170211	ETH.MESH.09170213
	Toglia The Mesh Story PPT	ETH.MESH.09214439	ETH.MESH.09214443
	Rousseau R Memo re Meeting Minutes of Project Planning Meeting	ETH.MESH.09264884	ETH.MESH.09264885
	Memo to Rousseau re Biocomp Risk Assess Prolene	ETH.MESH.09279161	ETH.MESH.09279161
	Notes re customers frustration with Ethicon rep	ETH.MESH.09293114	ETH.MESH.09293114
	Email from Jurgen Trzewik and attachment	ETH.MESH.09656790	
	Email from Jurgen Trzewik and attachment	ETH.MESH.09656792	
	Engel email chain re Gynemesh PS w/Monocryl	ETH.MESH.09664947	ETH.MESH.09664950
	Material specification spreadsheet	ETH.MESH.09671620	ETH.MESH.09671620
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	ETH.MESH.09905181 Abbrevo Lessons Learned - Preliminary Report Out	ETH.MESH.09905181	ETH.MESH.09905181
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	PT0-0746; Version 1 Validation Protocol for Knitting, Scouring and Heat-Setting 6-mil Old Construction Blue PROLENE Mesh at Secant Medical	ETH.MESH.862227	862235
	MS729-XXX; Appendix I Neuchatel Material Specification for TVT Prolene* Polypropylene Mesh Roll Stock	ETH.MESH.862284	ETH.MESH.862289

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DEPOSITIONS - TESTIMONY

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Arnaud, Axel, MD Transcripts and Exhibits	All dates
Barbolt, Thomas A., Ph.D Transcripts and Exhibits	10/10/2012; 08/04/2013; 08/15/2013; 01/07/2014; 01/08/2014
Batke, Boris Transcripts and Exhibits	8/1-2/2013
Beath, Catherine Transcripts and Exhibits	07/11-12/2013
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Hart, James D., MD Transcripts and Exhibits	09/17/2013; 12/20/2013
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DEPOSITIONS - TESTIMONY

Weisberg, Martin, MD Transcripts and Exhibits	All dates
Yale, Mark, Transcript and Exhibits	8/7/2013

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Abbas Shobeiri S, et al	The anatomy of midurethral slings and dynamics of neurovascular injury	Int Urogynecol J (2003) 14: 185-190
Abbott S, et al.	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Am J Obstet Gynecol 2014; 210:163.31-8
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